

Exhibit

“2”

Dionysios K. Veronikis, M.D.

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC,)	MASTER FILE
REPAIR SYSTEM PRODUCTS,)	NO. 2:12-MD-02327
LIABILITY LITIGATION)	
)	MDL NO. 2327
<hr/>		
THIS DOCUMENT RELATES TO)	
THE FOLLOWING CASES IN)	JOSEPH R. GOODWIN
wave 1 of 200:)	US DISTRICT JUDGE
MARIE BANKS, ET AL. V.)	
ETHICON, INC., ET AL)	
NO. 2:12-CV-01318)	
)	
ROBIN BRIDGES V.)	
ETHICON, INC., ET AL.)	
NO. 2:12-CV-00651)	
)	APRIL 30, 2016
DENNIS W. DIXON, ET AL.)	
V. ETHICON, INC., ET AL.)	
NO. 2:12-CV-01081)	
)	VIDEOTAPED DEPOSITION OF
PAULA FISK V.)	DIONYSIOS K. VERONIKIS, M.D.
ETHICON, INC., ET AL.)	
NO. 2:12-CV-00848)	
)	
SHERRY FOX, ET AL. V.)	
ETHICON, INC., ET AL.)	
NO. 2:12-CV-00878)	
)	
LOUISE GRABOWSKI V.)	
ETHICON, INC., ET AL.)	
NO. 2:12-CV-00683)	
)	
NANCY HOOPER, ET AL. V.)	
ETHICON, INC., ET AL.)	
NO. 2:12-CV-00493)	
)	
WILMA JOHNSON V.)	
ETHICON, INC., ET AL.)	
NO. 2:11-CV-00809)	
)	
LAURA WAYNICK, ET AL. V.)	
ETHICON, INC., ET AL.)	
NO. 2:12-CV-01151)	

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<p style="text-align: right;">Page 2</p> <p>1 VIRGINIA WHITE, ET AL. V.) 2 ETHICON, INC., ET AL.) 3 NO. 2:12-CV-00958) 4) 5 JULIE WROBLE, ET AL. V.) 6 ETHICON, INC., ET AL.) 7 NO. 2:12-CV-00883) 8 9 SATURDAY, APRIL 30, 2016 10 11 --- 12 13 Videotaped deposition of Dionysios 14 K. Veronikis, M.D., held at the Hilton St. 15 Louis – Frontenac, 1335 South Lindbergh 16 Boulevard, Frontenac, Missouri, commencing at 17 8:55 a.m., on the above date, before Carrie 18 A. Campbell, Registered Merit Reporter, 19 Certified Realtime Reporter, Illinois, 20 California and Texas Certified Shorthand 21 Reporter, and Missouri Certified Court 22 Reporter. 23 --- 24</p>	<p style="text-align: right;">Page 4</p> <p>1 APPEARANCES: 2 3 BLASINGAME BURCH GARRARD ASHLEY, PC 4 BY: JAMES B. MATTHEWS, ESQUIRE 5 jbm@bbgbalaw.com 6 440 College Avenue 7 Athens, Georgia 30601 8 (706) 354-4000 9 10 AYLSTOCK, WITKIN, KREIS & OVERHOLTZ, 11 PLLC 12 BY: MARY LIU, ESQUIRE 13 mliu@awkolaw.com 14 17 East Main Street, Suite 200 15 Pensacola, Florida 32502 16 (850) 202-1010 17 Counsel for Plaintiffs 18 19 BRYAN CAVE, LLP 20 BY: DAN H. BALL, ESQUIRE 21 dhsball@bryancave.com 22 JAMES P. EMANUEL, JR., ESQUIRE 23 James.Emanuel@bryancave.com 24 211 North Broadway, Suite 3600 25 St. Louis, Missouri 63102 26 (314) 259-2000 27 Counsel for Defendants 28 29 ALSO PRESENT VIA TELEPHONE: 30 Mark Mueller, Mueller Law Office 31 --- 32 33 34</p>
<p style="text-align: right;">Page 3</p> <p>1 INDEX 2 PAGE 3 APPEARANCES..... 4 4 EXAMINATIONS 5 BY MR. BALL..... 5 6 BY MR. MATTHEWS..... 293 7 BY MR. BALL..... 295 8 9 EXHIBITS 10 No. Description Page 11 1 Notice of deposition 5 12 2 Rule 26 Expert Report of Dr. 13 13 Dionysios K. Veronikis TVT 14 15 3 Rule 26 Expert Report of Dr. 13 16 Dionysios K. Veronikis Gynecare PS 17 4 Thumb nail drive of documents 7 18 5 CD of documents 7 19 20 CERTIFICATE..... 296 21 ERRATA..... 298 22 ACKNOWLEDGMENT OF DEPONENT..... 299 23 LAWYER'S NOTES..... 300 24</p>	<p style="text-align: right;">Page 5</p> <p>1 DIONYSIOS K. VERONIKIS, M.D., 2 of lawful age, having been first duly sworn 3 to tell the truth, the whole truth and 4 nothing but the truth, deposes and says on 5 behalf of the Defendants, as follows: 6 7 DIRECT EXAMINATION 8 QUESTIONS BY MR. BALL: 9 Q. Would you tell us your name, 10 please? 11 A. Dionysios Veronikis, 12 D-i-o-n-y-s-i-o-s, V-e-r-o-n-i-k-i-s. 13 Q. Dr. Veronikis, my name is Dan 14 Ball, and I represent Ethicon. And I'm going 15 to be asking you some questions about the two 16 reports you've submitted in the federal court 17 litigation involving TVT® and involving 18 Gynemesh® PS. 19 You understand that? 20 A. Yes. 21 (Veronikis Exhibit 1 marked for 22 identification.) 23 QUESTIONS BY MR. BALL: 24 Q. So the first thing I'm going to</p>

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<p>1 do is mark as Exhibit 1 to your deposition</p> <p>2 and ask you to just briefly take a look at</p> <p>3 that.</p> <p>4 A. Yes.</p> <p>5 Q. Exhibit 1 is the notice to take</p> <p>6 this deposition, right?</p> <p>7 A. Yes.</p> <p>8 Q. And have you seen this before?</p> <p>9 A. Yes, sir. It was e-mailed to</p> <p>10 me by Mr. Matthews.</p> <p>11 Q. And there's an attachment to</p> <p>12 that asking you to bring various things to</p> <p>13 the deposition.</p> <p>14 Did you get a chance to look at</p> <p>15 that.</p> <p>16 A. I did, and I spoke with</p> <p>17 Mr. Matthews, and he said he would bring</p> <p>18 everything.</p> <p>19 Q. Now, so do you have anything, I</p> <p>20 guess, Mr. Matthews to produce with respect</p> <p>21 to the depo notice?</p> <p>22 MR. MATTHEWS: You want to --</p> <p>23 well, those boxes there contain the</p> <p>24 documents that are referenced as</p>	<p>1 CD which is?</p> <p>2 MR. MATTHEWS: His reports for</p> <p>3 each product and the footnotes for</p> <p>4 each product. The documents that</p> <p>5 reference -- that are referenced in</p> <p>6 the footnotes.</p> <p>7 MR. BALL: Great. Thank you</p> <p>8 for that.</p> <p>9 QUESTIONS BY MR. BALL:</p> <p>10 Q. Now, have you charged for your</p> <p>11 services in this case?</p> <p>12 A. Not yet.</p> <p>13 Q. Okay. Do you intend to?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. And what will be the</p> <p>16 basis for your charges?</p> <p>17 How will those be calculated?</p> <p>18 A. It's an hourly rate.</p> <p>19 Q. And what is that?</p> <p>20 A. It's a thousand dollars an</p> <p>21 hour.</p> <p>22 Q. And do you have an estimate as</p> <p>23 to how many hours you spent coming into the</p> <p>24 start of this deposition?</p>
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<p>1 footnotes in his reports in both of</p> <p>2 them. This thumb drive contains</p> <p>3 everything that he was sent and</p> <p>4 reviewed.</p> <p>5 MR. BALL: Okay.</p> <p>6 MR. MATTHEWS: There's -- if</p> <p>7 you don't want to take the boxes or</p> <p>8 mark them as exhibits, there's a --</p> <p>9 everything in those boxes is on a CD</p> <p>10 that I also brought with me.</p> <p>11 MR. BALL: So I think what I'll</p> <p>12 do is mark the thumb drive and the --</p> <p>13 or I don't even need to mark them. We</p> <p>14 can just -- yeah, I'll mark them.</p> <p>15 Mark them and that is the two CDs, I</p> <p>16 think it would be the most convenient</p> <p>17 way.</p> <p>18 (Veronikis Exhibits 4 and 5</p> <p>19 marked for identification.)</p> <p>20 MR. BALL: Exhibit 4 is a thumb</p> <p>21 drive which is?</p> <p>22 MR. MATTHEWS: All of his</p> <p>23 reference materials.</p> <p>24 MR. BALL: And Exhibit 5 is a</p>	<p>1 A. Could you -- just for</p> <p>2 preparation of this deposition?</p> <p>3 Q. Yeah, that's fair. I'm going</p> <p>4 to ask a series of them so we'll start off.</p> <p>5 First of all, to prepare the</p> <p>6 two reports that we're going to be talking</p> <p>7 about here today?</p> <p>8 A. So it's about 50 hours.</p> <p>9 Q. And any other work you've done</p> <p>10 in preparation for this deposition?</p> <p>11 A. I reviewed everything that they</p> <p>12 had sent me, and it was a ton of stuff.</p> <p>13 Q. And about how many hours was</p> <p>14 that?</p> <p>15 A. 300. 350. I didn't add up the</p> <p>16 numbers just yet.</p> <p>17 Q. Okay. So in connection with</p> <p>18 this deposition and these reports, you would</p> <p>19 estimate that you've spent in the</p> <p>20 neighborhood of 350 to 400 hours?</p> <p>21 A. Yes.</p> <p>22 Q. And what is your charge for</p> <p>23 deposition?</p> <p>24 A. It's 6,000 for half a day,</p>

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<p>1 10,000 for entire day.</p> <p>2 Q. How about two-thirds of a day,</p> <p>3 what is that?</p> <p>4 Is it done on some hourly basis</p> <p>5 or --</p> <p>6 A. If it's an hour and a half or</p> <p>7 two hours sometimes, I'll, just to be fair,</p> <p>8 that's what it is. If it takes a half day or</p> <p>9 a full day, I try to be fair and consistent.</p> <p>10 Q. And is that what your charge</p> <p>11 would be if you ever appeared for trial would</p> <p>12 be \$10,000 a day?</p> <p>13 A. Yes.</p> <p>14 Q. Does that include -- if you had</p> <p>15 to travel to West Virginia, would it be</p> <p>16 \$10,000 the day you travel over there?</p> <p>17 A. It would be traveling expenses</p> <p>18 and my day there.</p> <p>19 Q. So let's say you were going to</p> <p>20 testify on a Tuesday and you went over on a</p> <p>21 Monday, would it be \$10,000 for Monday and</p> <p>22 10,000 for Tuesday?</p> <p>23 A. No.</p> <p>24 Q. What would the Monday be?</p>	<p>1 Now, on this notice --</p> <p>2 Q. Yeah.</p> <p>3 A. -- there's only one patient</p> <p>4 that I've seen from this notice.</p> <p>5 Q. And I wasn't just limiting to</p> <p>6 that notice.</p> <p>7 A. Okay.</p> <p>8 Q. I was saying in general you've</p> <p>9 seen about ten patients, Ethicon litigation</p> <p>10 patients?</p> <p>11 A. Yes.</p> <p>12 Q. And they've been about 10 or</p> <p>13 \$12,000 per patient to do an examination and</p> <p>14 a report?</p> <p>15 A. Yes.</p> <p>16 Q. And review the records?</p> <p>17 A. Yes.</p> <p>18 Q. And then in those cases, you</p> <p>19 either have or in the process of giving</p> <p>20 depositions on those?</p> <p>21 A. I've been deposed on one</p> <p>22 patient.</p> <p>23 Q. Okay. And that's a \$6,000 per</p> <p>24 half day charge for that?</p>
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<p>1 A. My travel expenses.</p> <p>2 Q. Okay. You wouldn't charge for</p> <p>3 your time in traveling?</p> <p>4 A. No.</p> <p>5 Q. Okay. Now, you also served as</p> <p>6 an expert witness on individual cases?</p> <p>7 A. Yes.</p> <p>8 Q. How many of those involving</p> <p>9 Ethicon?</p> <p>10 A. In the patients I examined for</p> <p>11 everyone who sent or just Mr. Matthews?</p> <p>12 Q. Everyone.</p> <p>13 A. Maybe ten.</p> <p>14 Q. Ten patients?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. And do you have an</p> <p>17 estimate as to what your average billings</p> <p>18 were per case on each one of those?</p> <p>19 A. It depends on the number of</p> <p>20 records and the time. It varies from 7,</p> <p>21 8,000, depending on the records, to 12, 14.</p> <p>22 Q. So 10 to 12 would be a good</p> <p>23 estimate on average?</p> <p>24 A. Yes.</p>	<p>1 A. That was only two hours so I'll</p> <p>2 probably just submit for two hours. I think</p> <p>3 the Attorney Emanuel was there for that.</p> <p>4 Q. So that would be a couple</p> <p>5 thousand dollars?</p> <p>6 A. Right.</p> <p>7 Q. Okay. Now, aside from the two</p> <p>8 reports that we're going to talk about here</p> <p>9 today and the ten patients that you've seen</p> <p>10 approximately, have you done any other work</p> <p>11 related to litigation involving Ethicon?</p> <p>12 A. No.</p> <p>13 Q. Okay. Now, have you been</p> <p>14 retained by a plaintiff to testify in cases</p> <p>15 against any other mesh manufacturers?</p> <p>16 A. No.</p> <p>17 Q. Have you ever been engaged to</p> <p>18 testify by a mesh manufacturer or serve as an</p> <p>19 expert by a mesh manufacturer?</p> <p>20 A. No.</p> <p>21 (Veronikis Exhibits 2 and 3</p> <p>22 marked for identification.)</p> <p>23 QUESTIONS BY MR. BALL:</p> <p>24 Q. Exhibit 2 is a copy of the</p>

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<p>1 report and materials that accompany the</p> <p>2 report relating to TVT® in this litigation;</p> <p>3 is that right?</p> <p>4 A. Yes.</p> <p>5 Q. And Exhibit 3 is a copy of the</p> <p>6 report and materials that accompanied the</p> <p>7 report in this litigation related to</p> <p>8 Gynemesh® PS; is that right?</p> <p>9 A. Yes.</p> <p>10 Q. Now, pursuant to the court</p> <p>11 rules, do Exhibits 2 and 3 contain all of</p> <p>12 your opinions and bases for those opinions</p> <p>13 that you intend to express in this</p> <p>14 litigation?</p> <p>15 A. Up to this point, yes.</p> <p>16 MR. MATTHEWS: So we're on the</p> <p>17 same page, some people have been doing</p> <p>18 depositions when the deponent has</p> <p>19 given two reports by doing the</p> <p>20 deposition on one report and then a</p> <p>21 separate deposition on the second</p> <p>22 report. Some people have just taken</p> <p>23 five hours to do kind of a</p> <p>24 combination.</p>	<p>1 playing.</p> <p>2 MR. BALL: James, can you just</p> <p>3 send the few people, whoever you</p> <p>4 wish -- and I'm not questioning, I'm</p> <p>5 just saying I got different</p> <p>6 information -- and I just want to see</p> <p>7 what they said and see --</p> <p>8 MR. MATTHEWS: It was an</p> <p>9 agreement between Tom Cartmell and</p> <p>10 Brian Aylstock and Dave Thomas. And</p> <p>11 that's the way every deposition has</p> <p>12 been done so far.</p> <p>13 MR. BALL: I'm not disputing.</p> <p>14 I just want to --</p> <p>15 MR. MATTHEWS: I understand.</p> <p>16 That's fine.</p> <p>17 MR. BALL: -- trust and verify.</p> <p>18 MR. MATTHEWS: I'm just trying</p> <p>19 to get out of here earlier.</p> <p>20 QUESTIONS BY MR. BALL:</p> <p>21 Q. All right. Now, what I would</p> <p>22 like to do, first of all, is talk about what</p> <p>23 your practice is and has been the last</p> <p>24 several years.</p>
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<p>1 MR. BALL: I thought it was</p> <p>2 six.</p> <p>3 MR. MATTHEWS: It's five on the</p> <p>4 first, two on the second.</p> <p>5 MS. LIU: Three on the first.</p> <p>6 MR. MATTHEWS: I mean, three on</p> <p>7 the first, two on the second.</p> <p>8 MR. BALL: I was told three and</p> <p>9 three because there's two -- calm</p> <p>10 down.</p> <p>11 MR. MATTHEWS: It's three and</p> <p>12 two. And I don't care if you do five</p> <p>13 hours and combine them.</p> <p>14 MR. BALL: I'm going to do five</p> <p>15 hours and combine them because I'm not</p> <p>16 good enough to draw that line so</p> <p>17 precisely.</p> <p>18 MR. MATTHEWS: Fine with me.</p> <p>19 MR. BALL: Having said that, I</p> <p>20 will try to kind of go through mostly</p> <p>21 TVT® stuff and then mostly Gynemesh®</p> <p>22 PS stuff.</p> <p>23 MR. MATTHEWS: Doesn't matter</p> <p>24 as long as I know what game we're</p>	<p>1 All right?</p> <p>2 A. Sure.</p> <p>3 Q. Do you perform surgery for</p> <p>4 stress urinary incontinence?</p> <p>5 A. Yes, sir.</p> <p>6 Q. Okay. SUI?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. Do you perform surgery</p> <p>9 for prolapse?</p> <p>10 A. Yes.</p> <p>11 Q. Anterior, posterior, apical?</p> <p>12 A. Yes.</p> <p>13 Q. And of those two types of</p> <p>14 surgeries, which do you do more?</p> <p>15 A. It's hard to say. You get</p> <p>16 patients that present with predominantly</p> <p>17 prolapse symptoms and when you reduce that</p> <p>18 prolapse, they also have incontinence. You</p> <p>19 have other patients that present with a</p> <p>20 primary complaint of incontinence, you</p> <p>21 examine them and they have other defects.</p> <p>22 So you end up doing a lot. It</p> <p>23 might be fair to say, I don't know, 50/50.</p> <p>24 Q. Okay. Do you also do surgery</p>

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<p>1 to deal with issues related to mesh products</p> <p>2 that have already been implanted?</p> <p>3 A. Unfortunately.</p> <p>4 Q. Okay. How does that fall --</p> <p>5 which is more common, that surgery or the</p> <p>6 original surgeries that you do for prolapse</p> <p>7 or SUI?</p> <p>8 A. So I've limited the patients</p> <p>9 that I see with mesh complications and I try</p> <p>10 to balance that between 50 percent mesh</p> <p>11 complications and 50 percent primary</p> <p>12 patients.</p> <p>13 Q. Has that been the case for the</p> <p>14 past several years, or have the percentages</p> <p>15 differed?</p> <p>16 A. I've actually dialed it down a</p> <p>17 little bit.</p> <p>18 Q. Dialed what down?</p> <p>19 A. The number of patients that I</p> <p>20 will see with mesh complications.</p> <p>21 Q. Okay. What did it use to be</p> <p>22 percentage-wise?</p> <p>23 A. Oh, at one point it was 60,</p> <p>24 70 percent, and I'm in a training program and</p>	<p>1 are for SUI.</p> <p>2 Q. Vast majority of the removals?</p> <p>3 A. Yes.</p> <p>4 Q. Okay. Now, one of the products</p> <p>5 that we're going to be talking about here</p> <p>6 today is a TVT® device, true?</p> <p>7 A. Yes.</p> <p>8 Q. Made by Ethicon, true?</p> <p>9 A. Yes.</p> <p>10 Q. And have you ever implanted a</p> <p>11 TVT®?</p> <p>12 A. I think I did it once or twice.</p> <p>13 Q. Okay. When?</p> <p>14 A. When it first came out.</p> <p>15 Q. Do you have a specific</p> <p>16 recollection of that or not?</p> <p>17 A. I have a specific recollection</p> <p>18 because Hattie Loggie, who was the local rep,</p> <p>19 was very interested in obtaining my business</p> <p>20 since I do a large volume and that would be</p> <p>21 good for her.</p> <p>22 I know there were discussions</p> <p>23 after that they kept trying to get me to use</p> <p>24 it, but I was not happy with the approach to</p>
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<p>1 by doing more of the complicated mesh</p> <p>2 removals, the residents in training weren't</p> <p>3 getting enough of the educational-type of</p> <p>4 procedures that they need to participate in.</p> <p>5 It created some grief so I dialed it back a</p> <p>6 little bit.</p> <p>7 Q. And how long ago was it that it</p> <p>8 was 60 to 70 percent?</p> <p>9 A. 18 months ago.</p> <p>10 Q. So what is the -- what does</p> <p>11 that work out to annually if it's 50 percent,</p> <p>12 let's say, how many mesh complication</p> <p>13 surgeries per year?</p> <p>14 A. So in 2015, I removed 296</p> <p>15 implants. I did a total of 605 surgeries.</p> <p>16 Q. Very precise.</p> <p>17 The mesh implants that you</p> <p>18 removed, let's use last year, how many of</p> <p>19 those were for SUI as opposed to for</p> <p>20 prolapse?</p> <p>21 A. I have that number, but I don't</p> <p>22 have it off the top of my head. I looked at</p> <p>23 some different numbers in preparation for</p> <p>24 this, but I would say that the vast majority</p>	<p>1 implant the product or the product itself.</p> <p>2 So I kind of got pressured to try one because</p> <p>3 they said try one, and then I tried a second</p> <p>4 one, and I didn't do anymore.</p> <p>5 Q. And when was that?</p> <p>6 A. Early when it first came out,</p> <p>7 very early. Ballpark, 2000 to 2003.</p> <p>8 Q. That time period?</p> <p>9 A. Yes, sir.</p> <p>10 Q. What was it about the</p> <p>11 approach -- you said the approach and the</p> <p>12 product, I think that's the word you used?</p> <p>13 A. Yes.</p> <p>14 Q. What was it about that --</p> <p>15 A. Well --</p> <p>16 Q. -- that you were dissatisfied</p> <p>17 with?</p> <p>18 A. Yes. I was very used to doing</p> <p>19 synthetic slings, and being trained as a</p> <p>20 vaginal surgeon, I had ideas of what a safe,</p> <p>21 effective surgery should be. When I looked</p> <p>22 at the IFU and the videos for performing the</p> <p>23 surgery, it was apparent that the way that</p> <p>24 they wanted me to do it wasn't, in my</p>

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<p>1 opinion, safe.</p> <p>2 In the ones I did perform, I</p> <p>3 did not follow Ethicon's recommendations. I</p> <p>4 did what I normally do for slings and used</p> <p>5 their product.</p> <p>6 Q. What was it about the procedure</p> <p>7 that you considered to be unsafe?</p> <p>8 A. The procedure was supposed to</p> <p>9 start with a 1.5 centimeter incision, 1</p> <p>10 centimeter from the urethra medias. That</p> <p>11 area of the anatomy immunologically develops</p> <p>12 from the sinovaginal bulbs, and it's fused so</p> <p>13 you can't really gauge the depth of</p> <p>14 dissection accurately. And it's a</p> <p>15 curvilinear structure. It's a tube. So you</p> <p>16 really need to separate that structure much</p> <p>17 more precisely.</p> <p>18 So the way that the</p> <p>19 instructions were was to make an incision and</p> <p>20 then make a half-centimeter blunt dissection,</p> <p>21 and at the time they had the 5-millimeter</p> <p>22 trocar, and you're trying to take a round</p> <p>23 structure, a trocar, and compress it between</p> <p>24 the flap that you created and then they had</p>	<p>1 unsafe. It yielded a high risk of a bladder</p> <p>2 puncture and injury. So I didn't follow</p> <p>3 those.</p> <p>4 Q. Did you use the -- the</p> <p>5 procedure you did use, did you use the trocar</p> <p>6 that came with the sling?</p> <p>7 A. I used the trocar, but I didn't</p> <p>8 use the handle.</p> <p>9 Q. Okay. And just briefly how did</p> <p>10 your approach differ from what was</p> <p>11 recommended in the IFU?</p> <p>12 A. Sure.</p> <p>13 So I started my incision about</p> <p>14 the midanterior vaginal wall. I identified</p> <p>15 the vesicovaginal space. What that had me do</p> <p>16 is it identified the blood supply and the</p> <p>17 thickness of the vaginal wall. I carry that</p> <p>18 dissection all the way to the urethra medias.</p> <p>19 I separated the vaginal wall from the</p> <p>20 urethra. I then pierced the urogenital</p> <p>21 diaphragm, created a much larger than</p> <p>22 1-centimeter opening. I opened the</p> <p>23 retropubic space.</p> <p>24 I developed an instrument that</p>
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<p>1 the device inside, the guide wire, which</p> <p>2 really doesn't do anything if you really</p> <p>3 think about it -- but I don't want to get</p> <p>4 ahead of myself.</p> <p>5 So it was a 5-millimeter</p> <p>6 trocar, supposed to make a 5-millimeter</p> <p>7 incision and tunnel it a little bit. I had</p> <p>8 read Ulmsten's original report and in his</p> <p>9 original report you were supposed -- he said</p> <p>10 make .5 to 1 centimeter. So the difficulty I</p> <p>11 had was with the pressure that was required</p> <p>12 to pass the trocar, the snug fit between the</p> <p>13 vaginal wall and the urethra, which was a</p> <p>14 tubular structure, not moving the lateral</p> <p>15 bladder side wall. The guide wire would be</p> <p>16 like taking a pen and putting it into a water</p> <p>17 bottle; it's not going to move the sides in.</p> <p>18 And the safety aspects of doing a sling is to</p> <p>19 move the paravaginal retropubic space and</p> <p>20 open that up and move the bladder medially so</p> <p>21 when you pass that trocar, you're literally</p> <p>22 passing it through an open space.</p> <p>23 The technique that was</p> <p>24 described and asked me to do I thought it was</p>	<p>1 allows me to get on the side of the bladder</p> <p>2 between the obturator internus muscles and</p> <p>3 the bladder sidewall and push that bladder</p> <p>4 wall over. Holding in that blunt retractor,</p> <p>5 sort of like a trocar but it's blunt, so when</p> <p>6 you push it, it won't poke a hole. I was</p> <p>7 able to move the bladder and all of the</p> <p>8 structures to the posterior aspect of the</p> <p>9 abdominal wall. Then touching that blunt</p> <p>10 retractor with a sharp trocar, the only thing</p> <p>11 I pierced was the rectus muscles. I did that</p> <p>12 on both sides.</p> <p>13 Q. Which is what you wanted to</p> <p>14 pierce?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. Now, the instrumentation</p> <p>17 and the procedure that was in the IFU and</p> <p>18 with the TVT® back 15 years or so ago when</p> <p>19 you did this, is that the same -- has that</p> <p>20 before changed?</p> <p>21 Has Ethicon ever changed either</p> <p>22 for the TVT®, either its instrument or its</p> <p>23 recommended procedure?</p> <p>24 A. I'm going to ask a question.</p>

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<p>1 Q. Sure.</p> <p>2 A. You're assuming we're talking</p> <p>3 about retropubic slings?</p> <p>4 Q. Yes. That's all your report</p> <p>5 deals with.</p> <p>6 A. Yes, I didn't comment on TVT®</p> <p>7 Exact, but they did --</p> <p>8 Q. But your report is only about</p> <p>9 the TVT® retropubic sling?</p> <p>10 A. Yes, sir.</p> <p>11 Q. That's all I am talking about</p> <p>12 here. And if I ask about something else,</p> <p>13 I'll --</p> <p>14 A. Okay. They did change it and</p> <p>15 call it TVT® Exact where they changed the</p> <p>16 trocar a little bit and put a plastic sheath</p> <p>17 on the end of the mesh, but the tenets of the</p> <p>18 procedure pretty much stayed the same.</p> <p>19 Q. So the TVT® even through the</p> <p>20 TVT® Exact, both the instrument and the</p> <p>21 recommended technique have remained</p> <p>22 essentially the same?</p> <p>23 A. They have.</p> <p>24 And what it does is it takes a</p>	<p>1 used to use BARD Uretex.</p> <p>2 Q. So Caldera is a company?</p> <p>3 A. Yes, sir.</p> <p>4 Q. Does it have a brand within</p> <p>5 that company?</p> <p>6 A. I think the implant is called</p> <p>7 Desara.</p> <p>8 Q. And how long have you been</p> <p>9 using that?</p> <p>10 A. Since 2010.</p> <p>11 Q. Does that come with</p> <p>12 instrumentation?</p> <p>13 A. Instrumentation is provided,</p> <p>14 yes.</p> <p>15 Q. Do you use it?</p> <p>16 A. I do not.</p> <p>17 Q. And does it come with an IFU?</p> <p>18 A. It does.</p> <p>19 Q. Does the IFU give a recommended</p> <p>20 technique?</p> <p>21 A. It does.</p> <p>22 Q. Do you follow that technique?</p> <p>23 A. I do not.</p> <p>24 Q. Why do you not use the</p>
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<p>1 1-centimeter mesh and upon implantation, it</p> <p>2 forces it to fold in that 5-millimeter</p> <p>3 tunnel.</p> <p>4 Q. Do you have more criticism of</p> <p>5 the TVT® with respect to the procedure and</p> <p>6 the trocar instrumentation that's being used</p> <p>7 or with respect to the mesh itself?</p> <p>8 A. I have criticisms of the entire</p> <p>9 kit, and that kit consists of the delivery</p> <p>10 system and the mesh.</p> <p>11 Q. I know that.</p> <p>12 What I asked you is do you have</p> <p>13 criticism more of one than the other, the</p> <p>14 technique and the instrumentation on the one</p> <p>15 hand versus the mesh?</p> <p>16 A. I have criticism of both. I</p> <p>17 don't know which one would be more because</p> <p>18 they're sort of together. You really can't</p> <p>19 isolate the one from the other.</p> <p>20 Q. Now, what do you use</p> <p>21 polypropylene slings today for SUI?</p> <p>22 A. I do.</p> <p>23 Q. Okay. What product?</p> <p>24 A. I'm currently use Caldera. I</p>	<p>1 instrumentation that comes with the Desara?</p> <p>2 A. It's not designed quite right.</p> <p>3 Q. Okay. Do you believe it is, at</p> <p>4 least to some degree, unsafe, use of that</p> <p>5 instrumentation?</p> <p>6 A. I've never used it.</p> <p>7 Q. Okay. And you don't use it</p> <p>8 because you think it might be unsafe?</p> <p>9 A. I don't use it because I</p> <p>10 designed my own trocar that allows me more</p> <p>11 precision in how to handle it.</p> <p>12 The TVT® trocar had a handle on</p> <p>13 it. I didn't use the handle, but at least</p> <p>14 that handle was detachable. The Desara</p> <p>15 handles have a nondetachable handle. It</p> <p>16 gives you too much torque. So I developed a</p> <p>17 trocar that does -- that limits how much</p> <p>18 torque you apply. Makes it safer.</p> <p>19 Q. Is that your own special --</p> <p>20 does it have a name?</p> <p>21 A. No.</p> <p>22 Q. Okay. Is it commercially</p> <p>23 available?</p> <p>24 A. It can be but, no.</p>

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<p>1 Q. What do you mean?</p> <p>2 A. Well, if someone wanted it, I</p> <p>3 would make one for them.</p> <p>4 Q. But you're not trying to</p> <p>5 commercially develop them?</p> <p>6 A. Oh, no. No.</p> <p>7 Q. Why don't you use the Desara</p> <p>8 technique?</p> <p>9 A. All of the techniques are</p> <p>10 pretty much the same for all the slings.</p> <p>11 They all want you to do it kind of the same</p> <p>12 way.</p> <p>13 Q. The way you described on the</p> <p>14 TVT®?</p> <p>15 A. Yes, sir.</p> <p>16 Q. Okay. And for the reasons</p> <p>17 you've described, you don't find that</p> <p>18 acceptable and you use the technique that you</p> <p>19 described earlier?</p> <p>20 A. Yes.</p> <p>21 Furthermore, the Desara product</p> <p>22 doesn't have a tubular attachment to it so it</p> <p>23 allows me to tailor the surgery to my own</p> <p>24 preferences as opposed to being confined.</p>	<p>1 A. Yes.</p> <p>2 Q. And you did not use that</p> <p>3 technique?</p> <p>4 A. I did not.</p> <p>5 Q. Okay. What was it about the</p> <p>6 Uretex instrument that made it acceptable to</p> <p>7 use and so you didn't use your own?</p> <p>8 A. It allowed me to pass the</p> <p>9 trocar without the sling. So I was able to</p> <p>10 create my exposure, dissect the vaginal wall,</p> <p>11 open it the way I like, dissect the</p> <p>12 retropubic space, pass the trocar, leave --</p> <p>13 at that point it was a little plastic tube --</p> <p>14 leave a little blue tube in position, remove</p> <p>15 the trocar, do the other side, not bring the</p> <p>16 sling into the field at all because it is</p> <p>17 sort of a contaminated area.</p> <p>18 So it allowed me to not bring</p> <p>19 the mesh on to the field until I was ready to</p> <p>20 implant it. Because if you have a bladder</p> <p>21 puncture, you had bleeding, the patient was</p> <p>22 stooling on the table, you know, you had</p> <p>23 complete control of it, which is what I'm</p> <p>24 able to do with Desara, which is what I did</p>
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<p>1 It's not as easy to do that</p> <p>2 with some of the other slings.</p> <p>3 Q. Including the TVT®?</p> <p>4 A. Yes.</p> <p>5 Q. You said you used a BARD</p> <p>6 product before the Desara?</p> <p>7 A. Yes.</p> <p>8 Q. And what was the name of that?</p> <p>9 A. Uretex.</p> <p>10 Q. And did that have an</p> <p>11 instrumentation to be used?</p> <p>12 A. It did.</p> <p>13 Q. Did you use it?</p> <p>14 A. I did.</p> <p>15 Q. Okay. Did you think it was</p> <p>16 good?</p> <p>17 A. It was good.</p> <p>18 Q. Okay. Why did you change from</p> <p>19 Uretex to Desara?</p> <p>20 A. The company got sold. I</p> <p>21 couldn't get it anymore.</p> <p>22 Q. And in terms of technique, was</p> <p>23 the technique recommended with the Uretex</p> <p>24 about the same as the TVT® and the Desara?</p>	<p>1 for my first sling.</p> <p>2 So the slings I have used have</p> <p>3 been an Ethicon Mersilene from '94 to 2003 --</p> <p>4 Q. Did you think that was a safe</p> <p>5 product?</p> <p>6 A. I did at the time.</p> <p>7 Q. Do you today?</p> <p>8 A. Its properties as an implant</p> <p>9 are questionable. It deteriorates.</p> <p>10 Q. But --</p> <p>11 A. So from then, the reason I</p> <p>12 changed was I wanted a less invasive sling.</p> <p>13 When you used a completely</p> <p>14 home-crafted sling, you made incisions that</p> <p>15 were 5 centimeters on the each side. Almost</p> <p>16 looked like an hernia repair, more invasive,</p> <p>17 took more OR time.</p> <p>18 Q. That was the Mersilene?</p> <p>19 A. That was the Mersilene.</p> <p>20 But it worked fine. Had a very</p> <p>21 high success rate. Steve Young did a paper</p> <p>22 on it with good outcomes, few complications,</p> <p>23 and then the trend was to do less invasive</p> <p>24 surgery. Data came out that polyethylene</p>

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<p>1 terephthalate, which is what Mersilene was, 2 may be degrading a little bit. I certainly 3 didn't want that. 4 It was touted that 5 polypropylene was the next great material. 6 It was less invasive, and I developed a 7 technique that was very similar to the 8 Mersilene placement, which I was very 9 comfortable with, which I knew what the 10 outcomes were, and went to Uretex. 11 Q. Okay. So '94 to 2000 was 12 Mersilene, and then 2000 to 2010 was Uretex, 13 or did I miss anything in between? 14 A. Close. 15 So '94 to about 2003. 16 Q. Okay. Was Mersilene? 17 A. Mersilene. 18 I also didn't like the TVT®. I 19 was kind of spoiled. When I handled the 20 Mersilene, it didn't fray, it didn't fall 21 apart. I could manipulate the edges. I 22 could suture the edges. There was things 23 that I could do to it that I still do 24 surgically that I could not do with the TVT®.</p>	<p>1 Mersilenes to clarify. There's Mersilene 2 mesh, which comes in a sheet which is about 3 10 inches by 10 inches, and there's Mersilene 4 ribbon, which is used for cerclage, which is 5 actually one of the first uses of a sling was 6 by Tiffany Williams and TeLinde in '62. It 7 was a very similar TVT®, small needles, and 8 they used it for cerclage -- 9 Q. Which did you use? 10 A. The Mersilene mesh. 11 Q. The sheet? 12 A. Yes, sir. And I would cut it, 13 like you said. 14 Q. Okay. And then from '03 to 15 '10, you used the BARD Uretex until it wasn't 16 sold anymore, and then from '10 forward the 17 Desara? 18 A. Yes. 19 Q. Now, do you know or have any 20 opinion today as to -- what else is out 21 there? 22 There's the TVT®? 23 A. Yes. 24 Q. And the various iterations of</p>
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<p>1 One of the things with 2 Mersilene is that it has a bias. So the 3 first thing I did, knowing that, and I didn't 4 know any better, was I pulled on the TVT® and 5 it frayed. 6 Q. Is Mersilene still sold for 7 sling repairs? 8 A. It was never really sold for 9 sling repairs. It was sold as a product that 10 you used as a surgeon as you saw fit. 11 Q. Okay. Did you have to cut it 12 for a particular surgery? 13 A. Yes. 14 Q. Okay. Did it come with its own 15 instruments? 16 A. It did not. 17 Q. Okay. So just so I've got the 18 timeline. 19 '94 to 2003, the Mersilene 20 product from Ethicon? 21 A. Yes. 22 Q. Which was called what, just 23 called Mersilene? 24 A. Yeah, just -- well, there's two</p>	<p>1 the TVT®? 2 A. Yes. 3 Q. And then there's Desara? 4 A. That's Desara. 5 Q. What else? 6 A. There's Advantage and Advantage 7 Fit by Boston Scientific. 8 Q. Okay. 9 A. There was a line by BARD. 10 There is the Supris by Coloplast. And I'm 11 not sure if I'm missing anyone. 12 Q. Have you used any of those 13 other ones that you just mentioned, the 14 Coloplast, the BARD Align or the Boston 15 Scientific one? 16 A. I used the Align when -- 17 because BARD was the import of Sofradim from 18 France. 19 When they were no longer able 20 to get it, they said they were coming out 21 with a sling. I tried it. I did not like 22 the characteristics. I confirmed that sling 23 was -- didn't have the same characteristics 24 as the Uretex. When I would operate at a</p>

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<p>1 certain hospital, the only product they had</p> <p>2 was Boston Scientific so they would not get</p> <p>3 me the Desara. So on a few cases I had to</p> <p>4 use the Boston Scientific product.</p> <p>5 Q. What hospital was that?</p> <p>6 A. St. Anthony's.</p> <p>7 Q. Okay.</p> <p>8 A. I stopped going there because</p> <p>9 of that.</p> <p>10 Q. Okay. Did you think that was</p> <p>11 an acceptable product or not?</p> <p>12 A. Very heavy. It had the same</p> <p>13 limitations as the TVT® Exact. It's a flat,</p> <p>14 1-centimeter piece of mesh rolled and</p> <p>15 attached to almost like a straw where you put</p> <p>16 the trocar through there.</p> <p>17 Again, I didn't follow the</p> <p>18 manufacturer's instructions.</p> <p>19 Q. All right. Now, of those that</p> <p>20 have been on the market the last several</p> <p>21 years, do you have any opinion or impression</p> <p>22 as to which has been most commonly used by</p> <p>23 surgeons for SUI?</p> <p>24 A. I don't.</p>	<p>1 Q. And have you ever had to remove</p> <p>2 all or a portion of a sling implanted by you?</p> <p>3 A. I release slings for some</p> <p>4 voiding difficulty. I cut them in the</p> <p>5 middle.</p> <p>6 Q. Have you ever had to remove a</p> <p>7 sling or a portion of a sling?</p> <p>8 A. I've reviewed --</p> <p>9 Q. Implanted by you?</p> <p>10 A. Yes, I've removed a sling I've</p> <p>11 implanted.</p> <p>12 Q. How many?</p> <p>13 A. To my knowledge, one.</p> <p>14 Now, that was a lady that had a</p> <p>15 previous TVT®, had a failure. I got a sling,</p> <p>16 a second sling, and was still having</p> <p>17 incontinence. So what I did is I removed</p> <p>18 both the TVT® and my sling to start over.</p> <p>19 Q. Is it your testimony that the</p> <p>20 TVT® procedure kit, product, is so unsafe</p> <p>21 that it never should be on the market?</p> <p>22 A. I think the risks far outweigh</p> <p>23 the benefits.</p> <p>24 Q. So it never should have been</p>
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<p>1 Q. So you don't know which one is</p> <p>2 the biggest seller, so to speak?</p> <p>3 A. No, but I see how many of each</p> <p>4 I remove, and it's -- the TVT® is maybe a</p> <p>5 little bit higher because the brand name was</p> <p>6 really smart marketing, TVT®. It was the</p> <p>7 first on the market so it had a large market</p> <p>8 share. So probably the TVT® is a little more</p> <p>9 popular maybe.</p> <p>10 Q. Have you ever had to remove a</p> <p>11 BARD -- I've already forgotten the name.</p> <p>12 A. Align.</p> <p>13 Q. No the one before that?</p> <p>14 A. Uretex?</p> <p>15 Q. Yes.</p> <p>16 Have you ever had to remove a</p> <p>17 BARD Uretex?</p> <p>18 A. Yes.</p> <p>19 Q. Several?</p> <p>20 A. Yes.</p> <p>21 Q. Have you ever had to remove a</p> <p>22 Desara?</p> <p>23 A. I removed a Desara TOT. I have</p> <p>24 not removed the Desara retropubic.</p>	<p>1 sold?</p> <p>2 A. No.</p> <p>3 Q. You agree with that?</p> <p>4 A. I agree with that.</p> <p>5 Q. Okay. Do you know anybody else</p> <p>6 in the world who agrees with that opinion</p> <p>7 that the TVT® never should have been sold?</p> <p>8 A. I don't know a lot of people so</p> <p>9 I'm really -- I really shouldn't -- can't</p> <p>10 answer that.</p> <p>11 Q. Well, the answer is you don't</p> <p>12 know anyone that shares that opinion, true?</p> <p>13 A. I think a more appropriate</p> <p>14 answer is I don't really talk about this</p> <p>15 stuff with other people too much about what</p> <p>16 their preferences are.</p> <p>17 Q. Is there any piece of</p> <p>18 literature or study, any piece of medical or</p> <p>19 scientific literature that you can point to</p> <p>20 that supports your opinion that the TVT®</p> <p>21 risks so outweigh its benefits that it never</p> <p>22 should have been on the market?</p> <p>23 A. It says that exact statement?</p> <p>24 Q. Or that supports that</p>

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<p>1 statement.</p> <p>2 A. I think there's papers that</p> <p>3 state that there's degradation of the mesh</p> <p>4 and there is a paper that says that the</p> <p>5 complications are not what's really reported</p> <p>6 in the literature. So some of the</p> <p>7 complications that were seen are skewed in a</p> <p>8 very specific way.</p> <p>9 Q. Okay. Which paper is that?</p> <p>10 A. I think her name was Anger.</p> <p>11 Q. And what's the paper that says</p> <p>12 there's degradation?</p> <p>13 A. That would be Clavé.</p> <p>14 Q. Was that in vivo degradation</p> <p>15 that was reported by Clavé?</p> <p>16 A. Yes.</p> <p>17 Q. So back to my original question</p> <p>18 because that wasn't quite -- I appreciate</p> <p>19 that information, but that wasn't quite the</p> <p>20 answer.</p> <p>21 Is there any paper you can</p> <p>22 point to that you believe reaches the</p> <p>23 conclusion -- I'll change it a little bit --</p> <p>24 that reaches the conclusion that the risks of</p>	<p>1 A. Several hundred.</p> <p>2 Q. Okay. Which has been studied</p> <p>3 more long term, the TVT® or the Desara sling?</p> <p>4 A. TVT®.</p> <p>5 Q. Are you familiar with the</p> <p>6 Nilsson 17-year study on the TVT®?</p> <p>7 A. I think I am.</p> <p>8 Q. Okay. Is that referenced in</p> <p>9 your report anywhere on TVT®?</p> <p>10 A. I don't think so.</p> <p>11 Q. You're aware of a -- it's a</p> <p>12 17 -- it's a study that followed women for up</p> <p>13 to 17 years with the TVT® and reported</p> <p>14 results.</p> <p>15 You know which study I'm</p> <p>16 talking about or not?</p> <p>17 A. I do.</p> <p>18 Q. Okay.</p> <p>19 A. I think there was two of them.</p> <p>20 I was hesitating for a second because I think</p> <p>21 there's a 2008 paper and there's one that</p> <p>22 came a few years after that. I think you're</p> <p>23 referring to the 2017 paper -- or is it 2017</p> <p>24 paper -- no, 17 years.</p>
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<p>1 TVT® outweigh the benefits so that it never</p> <p>2 should have been sold?</p> <p>3 A. I don't think that a lot of</p> <p>4 surgeons have the viewpoint that I have</p> <p>5 because they're not seeing these women with</p> <p>6 all these complications. Even I have not</p> <p>7 reported all my complications. Not my</p> <p>8 complications, the patients that present.</p> <p>9 So until that paper is written,</p> <p>10 I don't think that there's anyone that's</p> <p>11 going to support that view just yet.</p> <p>12 Q. So the answer to my question is</p> <p>13 you're not able to point to any study or any</p> <p>14 literature or any paper that expresses the</p> <p>15 opinion that you have that the risks of TVT®</p> <p>16 outweigh the benefits so that it never should</p> <p>17 have been sold?</p> <p>18 A. No paper that I know of.</p> <p>19 Q. Now, how many TVT®s have you</p> <p>20 removed?</p> <p>21 A. I can tell you what it was in</p> <p>22 2015. 34 retropubic.</p> <p>23 Q. Okay. Do you have any estimate</p> <p>24 as to how many you've removed in your career?</p>	<p>1 Q. We're not into 2017 so it can't</p> <p>2 be a 2017 paper.</p> <p>3 A. No, I do recall reading the</p> <p>4 paper.</p> <p>5 Q. Can you tell me why that paper</p> <p>6 is not referenced in your report?</p> <p>7 Let me back up. Let me</p> <p>8 withdraw the question and ask this.</p> <p>9 In your report, Exhibit 2,</p> <p>10 about the TVT®, did you attempt to get a fair</p> <p>11 and balanced assessment of the issues related</p> <p>12 to the TVT®?</p> <p>13 A. I did.</p> <p>14 Q. Okay. Did you in the report</p> <p>15 reference any literature that would be</p> <p>16 contrary to your opinion that the risks of</p> <p>17 the TVT® outweigh the benefits?</p> <p>18 Did you reference any papers</p> <p>19 like that in your report?</p> <p>20 A. I did.</p> <p>21 Q. Okay. And did you reference</p> <p>22 all of the papers in your report that would</p> <p>23 be contrary to that opinion?</p> <p>24 MR. MATTHEWS: Well, I</p>

12 (Pages 42 to 45)

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<p>1 didn't -- object to the form of the</p> <p>2 question.</p> <p>3 THE WITNESS: There are so many</p> <p>4 papers on TVT®, it's not possible to</p> <p>5 reference all the papers.</p> <p>6 QUESTIONS BY MR. BALL:</p> <p>7 Q. Okay. Why did you not</p> <p>8 reference the Nilsson 17-year study paper?</p> <p>9 A. I have a little problem with</p> <p>10 that paper. That paper started with 90</p> <p>11 patients, if I remember the one that's</p> <p>12 correct, and by the time they followed those</p> <p>13 patients, half -- they only followed half,</p> <p>14 which was 45 patients. That's not an</p> <p>15 adequate sample of a longitudinal study.</p> <p>16 Q. Which paper referenced in your</p> <p>17 report do you believe does not support your</p> <p>18 conclusion that the risks of TVT® outweigh</p> <p>19 the benefits?</p> <p>20 A. That would be the Thomas study,</p> <p>21 trial of midurethral sling.</p> <p>22 Q. What does it say?</p> <p>23 A. They compared retropubic sling</p> <p>24 to TOT to see if they both kind of were</p>	<p>1 the TVT®?</p> <p>2 A. There is.</p> <p>3 Q. Would you show me where that</p> <p>4 is?</p> <p>5 A. Sure.</p> <p>6 It's on page 9. It starts on</p> <p>7 page 9.</p> <p>8 It says the force required to</p> <p>9 implant the TVT® with the metal introducers</p> <p>10 deforms the mesh and the mesh can also deform</p> <p>11 after implantation. The design of the TVT®</p> <p>12 trocar, size, arc, handle with the TVT® mesh</p> <p>13 is a design mismatch for the pelvis --</p> <p>14 Q. I understand.</p> <p>15 I didn't get that one. Now</p> <p>16 with your explanation earlier, I understand</p> <p>17 what you're saying there.</p> <p>18 A. Okay.</p> <p>19 Q. So I appreciate that.</p> <p>20 A. Okay.</p> <p>21 Q. Do you believe that most</p> <p>22 doctors that -- well, strike that.</p> <p>23 The TVT® has been used millions</p> <p>24 of times in surgery over the years, true?</p>
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<p>1 equal. Partially because there's so many</p> <p>2 retropubic injuries and traumas from passage</p> <p>3 of those trocars, which, in my opinion, is</p> <p>4 related to the technique, and that report</p> <p>5 shows that at one year it seems like both</p> <p>6 slings are pretty equal. That's a good</p> <p>7 paper.</p> <p>8 The problem with the paper is</p> <p>9 it's only one year. It really didn't look at</p> <p>10 all the issues that occur years later. Most</p> <p>11 of these women that I'm seeing in my practice</p> <p>12 aren't showing up a year after a sling.</p> <p>13 They're showing up five, six, seven, eight,</p> <p>14 nine years later, and some of these problems</p> <p>15 have persisted for years.</p> <p>16 Q. The Thomas paper did not</p> <p>17 address the risk versus benefits of just the</p> <p>18 TVT®, did it?</p> <p>19 It was a comparison between the</p> <p>20 TVT® and the TVT-O?</p> <p>21 A. TVT®, TVT-O and Monarc.</p> <p>22 Q. Is there anywhere in Exhibit 2</p> <p>23 where you expressed criticism of the</p> <p>24 technique or instrumentation with respect to</p>	<p>1 A. I don't -- I'm sure. I don't</p> <p>2 know the exact number. I'll take your word</p> <p>3 for it.</p> <p>4 Q. You wouldn't disagree with</p> <p>5 that?</p> <p>6 A. No.</p> <p>7 Q. And the great majority of those</p> <p>8 times that it has been used, it's been</p> <p>9 successful?</p> <p>10 A. I don't know what the overall</p> <p>11 success rate in those millions is.</p> <p>12 Q. The great majority of the time</p> <p>13 that the TVT® has been used in surgery, it's</p> <p>14 been used with the instrumentation and the</p> <p>15 technique recommended by Ethicon, true?</p> <p>16 A. I don't know anyone else that's</p> <p>17 using the technique that I'm using.</p> <p>18 Q. Okay.</p> <p>19 A. Except my partner. I am sorry.</p> <p>20 Q. You don't know anyone else</p> <p>21 that's using any different technique than</p> <p>22 what's recommended by the --</p> <p>23 A. No. As I mentioned earlier,</p> <p>24 it's not something that I discuss with folks</p>

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<p style="text-align: right;">Page 50</p> <p>1 a lot.</p> <p>2 Q. Do you have an opinion as to</p> <p>3 what the success rate is with the -- if done</p> <p>4 by a surgeon using the technique and</p> <p>5 instrumentation recommended by the</p> <p>6 manufacturer, do you have an opinion as to</p> <p>7 what the success rate is with the TVT®?</p> <p>8 A. I do.</p> <p>9 Q. Okay. What is that opinion?</p> <p>10 A. The original success rate by</p> <p>11 Ulmsten was basically 85 percent cure. It</p> <p>12 was sadly 11 percent improvement. But it's</p> <p>13 85 percent cure, about 7 percent improvement,</p> <p>14 about 7, 8 percent didn't have an</p> <p>15 improvement. That was original data by</p> <p>16 Ulmsten.</p> <p>17 The data by the Thomas trial</p> <p>18 was a little bit less.</p> <p>19 Q. So what is your opinion with</p> <p>20 regard to the success rate of the TVT®, if</p> <p>21 you have an opinion?</p> <p>22 Based upon review of the</p> <p>23 literature, your own knowledge, do you have</p> <p>24 an opinion as to what the success rate is</p>	<p style="text-align: right;">Page 52</p> <p>1 lead to my next question.</p> <p>2 Do you have an opinion -- see</p> <p>3 if this was what you were getting ready to</p> <p>4 add.</p> <p>5 Do you have an opinion as to</p> <p>6 the percentage of complications? Is that</p> <p>7 what you're going to be talking about, or no?</p> <p>8 A. No.</p> <p>9 Q. What do you mean when you said</p> <p>10 for the percentage of the leaking part?</p> <p>11 A. That's what 85 percent success</p> <p>12 refers to, which is the testing they did</p> <p>13 afterwards on pad testing and cough stress</p> <p>14 test. That's how they measured the success.</p> <p>15 Q. So if it stopped completely,</p> <p>16 that was a cure?</p> <p>17 A. Yes.</p> <p>18 Q. And if it improved it, that was</p> <p>19 an improvement?</p> <p>20 A. Correct.</p> <p>21 Q. All right. I'm with you.</p> <p>22 Now, new question, do you have</p> <p>23 an opinion as to the complication rate -- and</p> <p>24 by that I don't mean temporary, I mean</p>
<p style="text-align: right;">Page 51</p> <p>1 with the TVT®?</p> <p>2 A. So my --</p> <p>3 MR. MATTHEWS: Hold on. Object</p> <p>4 to the form because I don't know what</p> <p>5 you mean by the definition of "success</p> <p>6 rate."</p> <p>7 QUESTIONS BY MR. BALL:</p> <p>8 Q. Okay. Go ahead.</p> <p>9 A. I read the papers, and I see</p> <p>10 numbers from 40 to 90. So my opinion is</p> <p>11 based on the success rate of those individual</p> <p>12 groups of patients that are reported. I have</p> <p>13 a very biased view because I see patients</p> <p>14 that have failure with leaking. And if</p> <p>15 you're only measuring the success rate, not</p> <p>16 leaking, it's about what those papers report.</p> <p>17 Q. Okay. So let me make sure. So</p> <p>18 your opinion would be that the success rate</p> <p>19 with TVT® is approximately 85 percent cure</p> <p>20 and about 7 percent improvement, and about 7</p> <p>21 or 8 percent no improvement?</p> <p>22 A. That's right. For the</p> <p>23 treatment of the leaking part.</p> <p>24 Q. Okay. I think that's going to</p>	<p style="text-align: right;">Page 53</p> <p>1 long-term complication rate -- with TVT®?</p> <p>2 A. I don't think that anyone can</p> <p>3 answer that question.</p> <p>4 Q. Okay. So you don't have an</p> <p>5 opinion?</p> <p>6 A. I have an opinion.</p> <p>7 Q. Okay. Your opinion, I can't</p> <p>8 answer it?</p> <p>9 A. Well, I can't give you a</p> <p>10 percentage. I guess what I was thinking, to</p> <p>11 be very transparent, give you a number like I</p> <p>12 gave you for the treatment of incontinence.</p> <p>13 I can't give you a number because I'm sure</p> <p>14 someone knows the denominator of how many</p> <p>15 slings went in, but -- or maybe the</p> <p>16 numerator, no one knows the other number of</p> <p>17 how many people are having problems. I know</p> <p>18 what problems I see, and I've not reported</p> <p>19 all these for any manufacturer.</p> <p>20 I know other doctors are taking</p> <p>21 care of problems. But there hasn't been a</p> <p>22 national registry in the United States that</p> <p>23 looks at how many went in and what the</p> <p>24 problems are.</p>

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<p>1 Q. Okay.</p> <p>2 A. And until that happens, it's</p> <p>3 hard to estimate.</p> <p>4 Q. Do you have -- do you tell your</p> <p>5 patients what the likelihood of complications</p> <p>6 is with -- in terms of percentages with an</p> <p>7 SUI procedure?</p> <p>8 A. The way I do it and what I do,</p> <p>9 yes, I do.</p> <p>10 Q. What do you say?</p> <p>11 A. 2 percent retention rate.</p> <p>12 Q. 2 percent will have a retention</p> <p>13 problem?</p> <p>14 A. 2 percent will have a retention</p> <p>15 problem requiring an adjustment of the sling,</p> <p>16 not a removal.</p> <p>17 Q. Okay. Can you tell me anything</p> <p>18 else about complication rates?</p> <p>19 A. Bleeding.</p> <p>20 Q. Can you give percentages on any</p> <p>21 of these?</p> <p>22 A. It's very rare. I've not</p> <p>23 transfused a patient from an SUI procedure in</p> <p>24 years.</p>	<p>1 Like if you take all of your</p> <p>2 SUI treatments in the last few years, what</p> <p>3 percentage has been non-mesh?</p> <p>4 A. It's going up. It's about</p> <p>5 15 percent now.</p> <p>6 Q. 15?</p> <p>7 A. 15.</p> <p>8 Q. What methods do you use?</p> <p>9 A. Either autologous fascia or</p> <p>10 cadaveric fascia.</p> <p>11 Q. Autologous means what?</p> <p>12 A. I remove a little bit of fascia</p> <p>13 from the patient's own body.</p> <p>14 Q. Where do you remove it from?</p> <p>15 A. Either the abdomen or the leg.</p> <p>16 It depends whether they have had hip</p> <p>17 replacement or if they've had multiple</p> <p>18 surgeries.</p> <p>19 Q. And what do you do, fashion a</p> <p>20 sling out of that?</p> <p>21 A. Yes. It's a basically a small</p> <p>22 little strip.</p> <p>23 Q. And then cadaveric is the same?</p> <p>24 A. Yes.</p>
Page 55	Page 57
<p>1 I talk about bladder injury</p> <p>2 because I get patients that have previous</p> <p>3 slings or previous other procedures.</p> <p>4 Q. Now, I'm going to get into all</p> <p>5 of the possible complications here in a</p> <p>6 minute.</p> <p>7 What I was asking is in terms</p> <p>8 of in your practice over the last 10 or</p> <p>9 15 years, have you given patients any</p> <p>10 percentage? And you mentioned that you tell</p> <p>11 them there's a 2 percent urinary retention.</p> <p>12 A. Incomplete bladder emptying</p> <p>13 retention.</p> <p>14 Q. Any other percentages that you</p> <p>15 give them?</p> <p>16 A. No.</p> <p>17 Q. In terms of complications?</p> <p>18 A. That's the only one, because</p> <p>19 all the other things with the technique I</p> <p>20 employ are exceedingly rare.</p> <p>21 Q. Do you ever use non-mesh for</p> <p>22 SUI?</p> <p>23 A. Yes, I do.</p> <p>24 Q. How often?</p>	<p>1 Q. It's a piece of tissue from</p> <p>2 another body?</p> <p>3 A. Yes.</p> <p>4 Q. That you fashion into a sling?</p> <p>5 A. Yes.</p> <p>6 Q. How is it -- or why is it that</p> <p>7 you use one of those two?</p> <p>8 Do you use either one of those</p> <p>9 more than the other?</p> <p>10 A. I give those options to the</p> <p>11 patient. Every patient with SUI now has a</p> <p>12 conversation regarding mesh and complications</p> <p>13 and what they've seen on the news and heard</p> <p>14 on the radio.</p> <p>15 Q. Do you have to use sutures in</p> <p>16 connection with those autologous or cadaveric</p> <p>17 slings?</p> <p>18 A. The approach I use is exactly</p> <p>19 the same whether I'm using synthetic,</p> <p>20 autologous or cadaver.</p> <p>21 Q. Do you have to use sutures?</p> <p>22 A. Yes.</p> <p>23 Q. And those are polypropylene</p> <p>24 sutures?</p>

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<p>1 A. No.</p> <p>2 Q. What are they?</p> <p>3 A. Polyglyconate suture. It's</p> <p>4 Vicryl Polysorb.</p> <p>5 Q. They're absorbable?</p> <p>6 A. Yes.</p> <p>7 Q. This 15 percent, is this just</p> <p>8 patient's choice?</p> <p>9 A. Yes.</p> <p>10 Q. Or do you recommend one versus</p> <p>11 the other?</p> <p>12 A. I give them the options.</p> <p>13 Q. Okay. And so that 15 percent</p> <p>14 now these days are choosing the cadaveric?</p> <p>15 A. Yes.</p> <p>16 Q. Or the autologous?</p> <p>17 Am I saying that right,</p> <p>18 autologous?</p> <p>19 A. Yes.</p> <p>20 Q. When did you start that?</p> <p>21 A. I've always done autologous</p> <p>22 slings.</p> <p>23 Q. No. I meant when did you start</p> <p>24 giving them, saying, "Here are the three</p>	<p>1 option.</p> <p>2 Q. How many of those do you think</p> <p>3 you've done in the last ten years?</p> <p>4 A. Last ten years?</p> <p>5 30, 40.</p> <p>6 Q. And that was when you already</p> <p>7 had to have an abdominal incision anyway?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. Is acute or chronic pain</p> <p>10 a risk of a non-mesh SUI surgery?</p> <p>11 A. Acute pain can be.</p> <p>12 Q. Not chronic pain?</p> <p>13 A. Huh-uh.</p> <p>14 Q. Is acute or chronic pain with</p> <p>15 intercourse a potential risk of non-mesh</p> <p>16 surgery?</p> <p>17 A. No.</p> <p>18 Q. So having pain with intercourse</p> <p>19 after an SUI surgery, non-mesh, is not a risk</p> <p>20 at all?</p> <p>21 A. It's virtually unheard of.</p> <p>22 Q. Is vaginal scarring a risk with</p> <p>23 non-mesh SUI surgery?</p> <p>24 A. Typically, no.</p>
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<p>1 choices, what do you want to do?"</p> <p>2 When did you start that?</p> <p>3 A. The last few years. I can't</p> <p>4 remember exactly when.</p> <p>5 Q. Okay. Other than any other</p> <p>6 type of -- you don't use the Burch procedure</p> <p>7 anymore?</p> <p>8 A. If they ask, but typically I'm</p> <p>9 doing a lot of vaginal surgery and the Burch</p> <p>10 procedure would necessitate an incision. If</p> <p>11 I'm doing --</p> <p>12 Q. An abdominal incision?</p> <p>13 A. Yes. If I'm doing an abdominal</p> <p>14 approach, when I'm right there.</p> <p>15 The reason I switched to a less</p> <p>16 invasive sling was not to make the abdominal</p> <p>17 incisions and et cetera.</p> <p>18 Q. Right.</p> <p>19 So you don't do very many</p> <p>20 Burches anymore?</p> <p>21 A. I never really did.</p> <p>22 Q. And how about MMK?</p> <p>23 A. It's a variation of a Burch. I</p> <p>24 always preferred the Burch, but the MMK is an</p>	<p>1 Q. Is infection a risk with</p> <p>2 non-mesh SUI surgery?</p> <p>3 A. You can get a hematoma and</p> <p>4 infection, yes.</p> <p>5 Q. Is urinary frequency, urgency,</p> <p>6 dysuria, retention or obstruction or</p> <p>7 incontinence, are those risks of non-mesh SUI</p> <p>8 surgery?</p> <p>9 A. Yes.</p> <p>10 Q. Are UTIs as a result of</p> <p>11 retention a risk of non-mesh SUI surgery?</p> <p>12 A. Yes.</p> <p>13 Q. Is organ or nerve damage a risk</p> <p>14 of non-mesh SUI surgery?</p> <p>15 A. Can be, yes.</p> <p>16 Q. Okay. Is bleeding a risk with</p> <p>17 non-mesh SUI surgery?</p> <p>18 A. Absolutely.</p> <p>19 Q. Wound complications?</p> <p>20 A. Sometimes.</p> <p>21 Q. Inflammation?</p> <p>22 A. Short-term inflammation.</p> <p>23 Q. Fistula formation?</p> <p>24 A. No.</p>

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<p>1 Q. How about are neuromuscular</p> <p>2 problems in the pelvic floor muscles, the</p> <p>3 lower extremities or the abdominal area, are</p> <p>4 those risks of non-mesh SUI surgery?</p> <p>5 A. I'm not sure I understand that</p> <p>6 last question.</p> <p>7 Q. Okay. You don't know what a</p> <p>8 neuromuscular --</p> <p>9 A. I do, but they were all kind of</p> <p>10 lumped together.</p> <p>11 Q. Okay. Can you have -- let me</p> <p>12 unlump then.</p> <p>13 Can you have neuromuscular</p> <p>14 problems in the pelvic floor muscles related</p> <p>15 to non-mesh SUI surgery?</p> <p>16 A. You can.</p> <p>17 Q. How about neuromuscular</p> <p>18 problems in the lower extremities?</p> <p>19 A. Not related to the procedure,</p> <p>20 no.</p> <p>21 Q. What about in the abdominal</p> <p>22 area?</p> <p>23 A. If you're harvesting the tissue</p> <p>24 from there, yes.</p>	<p>1 subject to potential foreign body responses?</p> <p>2 A. In the short term.</p> <p>3 Q. That type of suture, can it</p> <p>4 have erosion or exposure?</p> <p>5 A. Sometimes.</p> <p>6 Q. In a non-mesh SUI surgery?</p> <p>7 A. Yes.</p> <p>8 Q. And is contraction of tissues a</p> <p>9 risk in a non-mesh SUI surgery?</p> <p>10 A. No.</p> <p>11 Q. Okay. Now, is there any risk</p> <p>12 related to the mesh that is present with the</p> <p>13 TVT® mesh that is not present with the Desara</p> <p>14 mesh?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. What is that?</p> <p>17 A. The Desara does not fray. It's</p> <p>18 a very stable weave.</p> <p>19 Q. Okay. By fray, you mean what?</p> <p>20 On the edges?</p> <p>21 A. On the edges. It doesn't</p> <p>22 deform when you pull on it.</p> <p>23 Q. Okay. So have you ever seen</p> <p>24 evidence of fraying in any TVT® that caused</p>
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<p>1 Q. Okay. Is recurrent surgery a</p> <p>2 risk of non-mesh SUI surgery?</p> <p>3 A. Yes.</p> <p>4 Q. And is a foreign body response</p> <p>5 from sutures a risk of a non-mesh SUI</p> <p>6 surgery?</p> <p>7 A. If you use a polypropylene</p> <p>8 suture.</p> <p>9 Q. Okay. Are sometimes</p> <p>10 polypropylene -- is that an acceptable</p> <p>11 practice to use polypropylene sutures in</p> <p>12 non-mesh SUI surgery?</p> <p>13 A. Some do.</p> <p>14 Q. It's acceptable?</p> <p>15 A. I don't know if it's</p> <p>16 acceptable; some do.</p> <p>17 The tensile strength is</p> <p>18 different. Most will use a non-monofilament</p> <p>19 suture because if you touch it with the</p> <p>20 forceps or you tie it, it fractures and it</p> <p>21 breaks and it fails. So most of us that do</p> <p>22 different kinds of surgeries will use a</p> <p>23 non-monofilament polypropylene suture.</p> <p>24 Q. And is that type of suture</p>	<p>1 any clinical problem in your view?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. Tell me about that.</p> <p>4 A. So when I first started --</p> <p>5 first of all, when it first became blue is</p> <p>6 when it really became apparent. You would</p> <p>7 open up the anterior vaginal wall, you would</p> <p>8 actually see little curly pieces of portions</p> <p>9 of mesh stuck to the inside of the vaginal</p> <p>10 wall.</p> <p>11 Q. And what clinical issues were</p> <p>12 those causing?</p> <p>13 A. I'm getting there.</p> <p>14 Q. Okay.</p> <p>15 A. I'm getting to that. So that</p> <p>16 was the first observation. So that came off</p> <p>17 of the implant.</p> <p>18 So when you lose part of the</p> <p>19 weave, the mesh elongates and ropes and cords</p> <p>20 and twists and rolls, and as soon as it does</p> <p>21 that, it goes from being whatever its gram</p> <p>22 per meter squared weight is, it's immediately</p> <p>23 doubled.</p> <p>24 And the additional part that is</p>

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<p>1 very, very important is that the pores 2 coalesce. So whatever the pores -- when it's 3 sitting on the table before it's implanted, 4 once it's implanted with any type of force on 5 it, the pores -- the effective pore size 6 becomes very small. 7 Q. Have you ever measured the 8 effective pore size on a TVT®? 9 A. Personally, no. 10 Q. Okay. Are you aware of any 11 study that has done that? 12 A. I've seen documentation inside 13 the Ethicon documents that tells me what the 14 pore size it. 15 Q. In vivo? 16 A. Not in vivo. 17 Q. Okay. So do you have an 18 opinion as to what the effective pore size in 19 vivo is in a TVT®? 20 A. I do. 21 Q. Okay. What is it? 22 A. It's less than before it got 23 implanted. 24 Q. Do you have anything more</p>	<p>1 Q. Which is lighter weight, the 2 Desara or the TVT®? 3 A. They're the same weight. 4 Q. Okay. Which has larger pores, 5 the Desara or the -- what do you call it, the 6 opposite of in vivo? 7 When it comes out of the box, 8 which has larger pores, Desara or TVT®? 9 A. Desara. 10 Q. Do you know the dimensions of 11 the Desara sling? 12 A. You mean the pore size? 13 Q. Yeah. 14 A. Yeah, it's approximately 15 1,200 microns. 16 Q. What is the size of the TVT® 17 pores? 18 A. About a thousand microns. 19 Q. What is the size -- what was 20 the size of the Uretex? 21 A. 1,160. 22 Q. Do you have an opinion as to 23 what the pore size in the body is of the 24 Desara or the Uretex?</p>
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<p>1 precise than that? 2 A. Sometimes there is no pores. 3 It completely coalesces very easily. The 4 stretchability of the mesh is desirable, but 5 the problem with it is that it deforms so 6 much that it -- there's virtually no pore. 7 It's a tiny little slit. 8 Q. By the Amid classification is 9 the mesh in TVT® a large pore mesh? 10 A. By the Amid classification, 11 yes. 12 Q. In your view is it generally 13 recognized that the TVT® is a large pore 14 mesh? 15 A. Oh, by Ethicon's documentation 16 is considered microporous. 17 Q. In the medical community, is it 18 generally -- is the TVT® mesh generally 19 regarded as a macroporous mesh? 20 A. Before it's implanted, yes. 21 Q. In the medical community, is 22 the TVT® mesh generally regarded as 23 lightweight? 24 A. No.</p>	<p>1 A. I do. 2 Q. What is it? 3 A. It's greater than 1,160, 4 greater than 1,200. 5 Q. They get bigger? 6 A. I make them bigger. 7 Q. Okay. How do you do that? 8 A. I am sorry, I was a little 9 remiss. I didn't mention that when I place 10 the sling in the midurethra, I sew it in a 11 configuration -- I attach it with absorbable 12 sutures in a configuration that opens the 13 pores up more. 14 Q. Is that recommended in the IFUs 15 for either Uretex or Desara? 16 A. No. 17 Q. So if you didn't do that 18 technique, do you have an opinion as to what 19 the effective pore size would be for the 20 Desara or the Uretex? 21 A. I do not. 22 Q. It would be something less than 23 they're designed? 24 A. You would think so.</p>

18 (Pages 66 to 69)

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<p>1 Q. Okay.</p> <p>2 A. And when I tried to do that</p> <p>3 with TVT®, I couldn't because of the edges</p> <p>4 fraying.</p> <p>5 Q. Okay.</p> <p>6 A. When I tried those two. But I</p> <p>7 always thought that the pores on all the</p> <p>8 slings that came after the Ethicon Mersilene</p> <p>9 were small because I was spoiled. I was used</p> <p>10 to seeing large pores where I could open the</p> <p>11 tissue up and if you held and just looked for</p> <p>12 a second, you could actually see the turgor</p> <p>13 pressure of the tissue coming through the</p> <p>14 pores before the operation was done. So</p> <p>15 having that visual confirmation and then not</p> <p>16 having it with polypropylene made me think.</p> <p>17 Q. Did you think the pores, the</p> <p>18 preimplantation pore size, was larger in</p> <p>19 Mersilene?</p> <p>20 A. It's definitely larger.</p> <p>21 Q. What is it?</p> <p>22 A. 23 -- 2.3 millimeters.</p> <p>23 Q. 2,300?</p> <p>24 A. Yes.</p>	<p>1 Q. Could you do the same spreading</p> <p>2 out thing with the TVT®?</p> <p>3 A. You can't.</p> <p>4 Q. Why?</p> <p>5 A. Because the material frays.</p> <p>6 It's not just the mesh. It's not just the</p> <p>7 filament that's woven. It's the weave</p> <p>8 configuration, it's all proprietary.</p> <p>9 So the first thing I did when</p> <p>10 TVT® was cleared was I pulled on it on a</p> <p>11 piece of paper. Oh, my God, it's falling</p> <p>12 apart. And that's why I didn't want to try</p> <p>13 it.</p> <p>14 Q. It was falling apart, or what</p> <p>15 do you mean by that?</p> <p>16 A. Yeah, it was -- when you --</p> <p>17 Q. Pieces were coming off?</p> <p>18 A. Pieces were coming off.</p> <p>19 Drastically.</p> <p>20 Q. Have you read any study that</p> <p>21 the TVT® mesh falling apart, pieces coming</p> <p>22 off it, have been a clinical problem for</p> <p>23 anyone?</p> <p>24 A. I've read in the Ethicon</p>
Page 71	Page 73
<p>1 Q. Microns?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. I can't remember what</p> <p>4 you said. The Desara and the Uretex, were</p> <p>5 those lightweight meshes?</p> <p>6 A. So the Uretex was 81 grams per</p> <p>7 meter squared. So that was lighter than all</p> <p>8 the others. So if you take a look at all the</p> <p>9 current slings that are on the market,</p> <p>10 they're all at about 100. Boston Scientific,</p> <p>11 Desara, Align.</p> <p>12 Q. And TVT®?</p> <p>13 A. Yes, and they're all too heavy.</p> <p>14 Q. Okay.</p> <p>15 A. They're all too heavy.</p> <p>16 Q. Everything that's on the market</p> <p>17 today is too heavy?</p> <p>18 A. Everything that's on the market</p> <p>19 is a problem.</p> <p>20 Q. Is the pore size for the -- not</p> <p>21 counting you're spreading it out when you</p> <p>22 implant it, is the pore size acceptable on</p> <p>23 the Desara as far as you're concerned?</p> <p>24 A. Yes.</p>	<p>1 documents that people complained that it was</p> <p>2 fraying.</p> <p>3 Q. Have you read any published</p> <p>4 scientific literature where fraying and the</p> <p>5 TVT® mesh falling apart was recognized to be</p> <p>6 a problem?</p> <p>7 A. Not yet.</p> <p>8 Q. Okay. Talking about the</p> <p>9 Ethicon documents, do you, as a scientist --</p> <p>10 well, first of all, have you seen any Desara</p> <p>11 internal documents?</p> <p>12 A. I have not.</p> <p>13 Q. Okay. Have you seen any BARD</p> <p>14 internal documents?</p> <p>15 A. Not for slings.</p> <p>16 Q. About their slings?</p> <p>17 A. Not slings, no.</p> <p>18 Q. Do you generally in reaching</p> <p>19 medical opinions rely upon internal e-mails</p> <p>20 and internal documents?</p> <p>21 A. No.</p> <p>22 Q. Have you written -- have you</p> <p>23 published in the medical field?</p> <p>24 A. Yes.</p>

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<p>1 Q. Have you ever cited an internal 2 document when writing in a peer-reviewed 3 journal? 4 A. No. 5 Q. Do you think citations of 6 internal company documents in a peer-reviewed 7 journal would be acceptable? 8 A. No. 9 Q. Okay. Have you ever been a 10 reviewer? 11 A. Yes. 12 Q. Okay. And if you were given a 13 paper that based opinions upon internal 14 company documents, would you reject that 15 paper as a reviewer? 16 A. It's a good question. I don't 17 know what I would do. I would find it very 18 different because you don't normally have 19 that. 20 Q. Do you believe that you gave a 21 fair representation of the overall Ethicon 22 documents that you cited in your paper? 23 A. Yes. 24 Q. How many Ethicon documents did</p>	<p>1 what you've cited in your report? 2 Do you know that? 3 A. I don't know that. 4 Q. Were you given any testimony of 5 Ethicon witnesses to review? 6 A. Yes. 7 Q. Okay. Was that also sent to 8 you by the lawyer? 9 A. Yes. 10 Q. Is what was sent to you also on 11 the thumb drive and the CD? 12 A. I've not seen the thumb drive. 13 Q. Okay. 14 A. I've not opened it. The CD, I 15 believe, are my reports only. 16 Q. Does your report refer to all 17 of the deposition testimony that you've been 18 given? 19 A. No. 20 Q. Okay. How do I know which 21 testimony you've been given? 22 A. I guess it's on the thumb 23 drive. 24 Q. Okay. And so if there was --</p>
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<p>1 you review? 2 A. I reviewed everything they sent 3 me. I can't even tell you. 4 Q. That's a key part. 5 Did you review anything that 6 wasn't sent to you by a lawyer, an Ethicon 7 document that wasn't sent to you by a lawyer? 8 A. No. I wouldn't have access to 9 it. 10 Q. Do you know how many they sent 11 you? 12 A. Documents? 13 Q. Yes. 14 A. Thousands and thousands of 15 pages. 16 Q. Is everything they sent you on 17 the thumb drive or the CD, all the Ethicon 18 documents they sent you on the CD or the 19 thumb drive? 20 A. I believe that's what 21 Mr. Matthews said. 22 Q. Do you know whether there were 23 Ethicon documents that weren't sent to you 24 that would paint a different picture than</p>	<p>1 did you read all of the Ethicon testimony 2 that's been given? 3 A. Yes. 4 Q. It was on the thumb drive? 5 A. Yes. 6 Q. Every word of it? 7 A. To the best of my recollection, 8 yes, sir. 9 Q. Okay. Do you know whether you 10 were given all of the Ethicon testimony about 11 these documents? 12 A. I don't know. 13 Q. Okay. In order to do a -- 14 strike that. Back up. 15 To give a fair and balanced 16 report, it would not be appropriate to 17 cherry-pick from Ethicon testimony or Ethicon 18 documents, true? 19 A. True. 20 MR. BALL: I like to take a 21 break every hour. 22 Is that okay with everybody? 23 MR. MATTHEWS: You're right in 24 the middle of a question.</p>

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<p>1 MR. BALL: No, I was done with</p> <p>2 that question.</p> <p>3 MR. MATTHEWS: Yeah, that's</p> <p>4 fine.</p> <p>5 (Off the record at 10:04 a.m.)</p> <p>6 QUESTIONS BY MR. BALL:</p> <p>7 Q. Doctor, your reports that have</p> <p>8 been submitted in this case, Exhibits 2 and</p> <p>9 3, you would not submit those reports to a</p> <p>10 peer-reviewed journal for publication, true?</p> <p>11 A. They're not prepared for</p> <p>12 publication, no.</p> <p>13 Q. And you would not use the same</p> <p>14 technique and approach in preparing those</p> <p>15 cases that you would if you were preparing a</p> <p>16 scientific paper to be presented to</p> <p>17 colleagues, true?</p> <p>18 A. Yes. This is completely</p> <p>19 different.</p> <p>20 Q. Okay. Now, the fraying that</p> <p>21 you mentioned, did the Uretex have any of</p> <p>22 that propensity?</p> <p>23 A. No, it had a weave</p> <p>24 characteristic that I look for. So after</p>	<p>1 A. It did, but it was</p> <p>2 multi-filament and that was the problem with</p> <p>3 it, and I wanted to do the best for my</p> <p>4 patients, and knowing that, I switched.</p> <p>5 Q. So the standard became -- the</p> <p>6 acceptable standard was to use a lightweight,</p> <p>7 monofilament, macroporous mesh for slings,</p> <p>8 correct?</p> <p>9 A. Macroporous, monofilament. The</p> <p>10 weight issue really didn't become important</p> <p>11 for some time after that.</p> <p>12 Q. Would you classify all of the</p> <p>13 Uretex and the TVT® and the Desara all as</p> <p>14 lightweight or heavyweight?</p> <p>15 A. They're all heavyweight.</p> <p>16 Q. Are they recognized in the</p> <p>17 medical community to be heavyweight or</p> <p>18 lightweight?</p> <p>19 A. Heavyweight.</p> <p>20 Q. Okay. Now, as we've said</p> <p>21 earlier, obviously, at least hundreds, and</p> <p>22 probably thousands, of surgeons have used</p> <p>23 TVT® for SUI, true?</p> <p>24 A. Yes.</p>
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<p>1 TVT® came out -- and I remember it was Will</p> <p>2 Irby that came and talked to me about it -- I</p> <p>3 didn't find another product that I thought</p> <p>4 met my characteristics, qualifications -- the</p> <p>5 characteristics of the Mersilene, until I saw</p> <p>6 Uretex, and the weave was in such a way that</p> <p>7 it did not fray.</p> <p>8 Q. Now, was the Uretex heavier or</p> <p>9 lighter -- excuse me, the Mersilene, was that</p> <p>10 heavier or lighter?</p> <p>11 A. Much lighter. 33 grams per</p> <p>12 meter squared.</p> <p>13 Q. And why was it that the</p> <p>14 Mersilene -- what about it caused it to</p> <p>15 deteriorate early as you said earlier?</p> <p>16 A. Well, I don't know that it</p> <p>17 deteriorated early. I didn't have those</p> <p>18 issues. But as it became more important to</p> <p>19 have Amid-type classifications -- and the</p> <p>20 Amid classification really was very important</p> <p>21 after the Gore-Tex because you needed</p> <p>22 75 microns or larger to have macrophages</p> <p>23 fight the infection.</p> <p>24 Q. Mersilene had that, didn't it?</p>	<p>1 Q. Okay. Are you critical of all</p> <p>2 of those surgeons for using a product that</p> <p>3 should never have been on the market?</p> <p>4 A. I don't think they knew all of</p> <p>5 the things I knew or have my experience so I</p> <p>6 can't be critical of them.</p> <p>7 Q. And by your experience, that</p> <p>8 means the one or two times you tried it?</p> <p>9 A. No. No. No.</p> <p>10 My experience with being a</p> <p>11 surgeon of last resort that sees patients</p> <p>12 that have problems.</p> <p>13 For example, even in this</p> <p>14 community, Dr. Klutke was a preceptor for</p> <p>15 TVT®, and he would do surgery on patients,</p> <p>16 and those patients would have a problem. And</p> <p>17 they would then come to me. And I frankly</p> <p>18 would ask because Dr. Klutke was a professor</p> <p>19 of urology. He was one of the earlier</p> <p>20 adapters of the TVT®. He went to France and</p> <p>21 all of those things. And I am not sure he</p> <p>22 knew how to deal with the complications or</p> <p>23 I'm not sure exactly why, but those patients</p> <p>24 ended up with me, and I started to see a</p>

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<p>1 pattern of problems. The more I did that, 2 the more patients found out and more docs 3 found out I could help these problems and 4 pretty soon I'm in the situation I'm in. 5 Q. Have any of the complications 6 that you've seen with the TVT® been related 7 to improper surgical technique? 8 A. They follow the technique 9 that's described. When I read the op notes, 10 it reads like the way Ethicon set up the IFU. 11 Q. Well, can a surgeon attempt to 12 follow what is set forth in the Ethicon IFU 13 and make a mistake and not -- and then that 14 leads to a complication? 15 A. They can change a technique 16 like I've changed it, but can that be a 17 mistake in the hands of others? I assume so. 18 Q. So is it fair to say that your 19 opinion that the TVT® should never have been 20 sold based upon you using it one or two times 21 and -- the fact that it was based primarily 22 upon using it one or two times and what you 23 see from the people with complications? 24 A. Would you repeat that?</p>	<p>1 were alternatives available for different 2 products to be developed, I may have put in a 3 bunch of slings and I may have, you know, 4 done it for -- not knowing what the 5 consequences were. 6 Q. Did Mersilene have a foreign 7 body reaction? 8 A. It did. 9 Q. What was it made out of? 10 A. Polyethylene terephthalate. 11 Q. Was the foreign body reaction 12 any different with Mersilene than with 13 polypropylene? 14 A. I'm sure it's different. 15 Q. Worse? Better? 16 A. I don't know. I haven't seen 17 any data on that. 18 Q. You mentioned foreign body 19 reaction. 20 The other thing was, what, 21 deterioration of polypropylene, is that what 22 you said? 23 A. Yes. 24 Q. Did Mersilene deteriorate?</p>
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<p>1 Q. Yeah. 2 Is your opinion that the TVT® 3 never should have been on the market based 4 upon the one or two times you tried it and 5 the complications you've seen with people 6 that have come to you postsurgery? 7 A. Plus everything that I've read 8 to date. 9 Q. What is it that you've read to 10 date specifically that -- or what are the two 11 or three things you've read to date that are 12 most important to you in your opinion that it 13 never should have been on the market? 14 A. So I'm having a little 15 difficulty even in my own practice anymore 16 using polypropylene knowing that there's a 17 chronic foreign body reaction, knowing that 18 polypropylene degrades. I don't know how I'm 19 going to personally deal with that. I'm 20 going to have come up with an alternative 21 source. Maybe going to completely cadaver 22 types of slings. 23 But knowing what I know now 24 after reading all of this, knowing that there</p>	<p>1 A. Not like polypropylene. 2 Q. Okay. So the polypropylene 3 slings that you've used, aside from the one 4 or two times with TVT®, essentially are the 5 Uretex and Desara? 6 A. Yes. 7 Q. And they're subject to chronic 8 foreign body reaction? 9 A. Yes. 10 Q. They're subject to 11 deterioration? 12 A. Yes. 13 Q. You're still using them? 14 A. I am. 15 Q. Have for 13 years? 16 A. Yes. 17 Q. Implanted thousands? 18 A. Yes. 19 Q. Have you ever told any of your 20 patients that you shouldn't have used 21 polypropylene because of its deterioration or 22 foreign body reaction propensities? 23 A. I'm saying that to patients 24 now.</p>

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<p>1 Q. And you started that a year or 2 so ago?</p> <p>3 A. Yes.</p> <p>4 Q. What problems does the chronic 5 foreign body reaction cause?</p> <p>6 Let me withdraw that question 7 and ask something better.</p> <p>8 You can have a chronic foreign 9 body reaction that doesn't cause any symptoms 10 to the patient, true?</p> <p>11 A. I'm sure you can to some 12 extent, yes.</p> <p>13 Q. And are you aware of any 14 studies that have shown that a chronic 15 foreign body reaction causes problems for 16 patients?</p> <p>17 A. Yes.</p> <p>18 Q. What is that?</p> <p>19 A. The problem is that it 20 contracts. The chronic foreign body reaction 21 and the -- a lot because of the pore size it 22 creates this granuloma-type of effect and 23 entraps little nerves. Instead of the pores 24 being far apart and the nerves being padded</p>	<p>1 in a thousand, one in 22,000.</p> <p>2 Q. With your technique?</p> <p>3 A. With my technique.</p> <p>4 But it's not 10, 12 percent.</p> <p>5 Q. So let me make sure, as I go 6 through these questions what I'm asking for 7 is with the Desara or the Uretex, if you 8 follow the manufacturer's instructions and 9 you use the manufacturer's technique.</p> <p>10 A. Okay.</p> <p>11 Q. That's the premise.</p> <p>12 A. Okay.</p> <p>13 Q. All right. So can you have 14 acute and chronic pain with Desara and 15 Uretex?</p> <p>16 A. Following the manufacturer's 17 technique, yes.</p> <p>18 Q. Can you have acute and chronic 19 pain with intercourse with Desara and Uretex?</p> <p>20 A. Yes.</p> <p>21 Q. Can you have vaginal scarring 22 with Uretex and Desara?</p> <p>23 A. Yes.</p> <p>24 Q. Can you have infection?</p>
Page 87	Page 89
<p>1 with fat infiltration, the nerve gets 2 squeezed over time and that chronic 3 inflammation continues to contract and it 4 creates contraction in the vagina. So when 5 you examine these patients, you feel a 6 tethering effect like a banjo string or a 7 rope, and that causes pain.</p> <p>8 Q. Do you have acute or chronic 9 pain with Desara and Uretex slings?</p> <p>10 A. Can you? Yes.</p> <p>11 Q. That's a risk?</p> <p>12 A. Yes.</p> <p>13 Q. And acute or chronic pain with 14 intercourse, is that a risk of SUI surgery 15 with Uretex or Desara?</p> <p>16 A. Can I qualify the answer?</p> <p>17 Q. You can say yes first and then 18 qualify.</p> <p>19 A. Yes, you can, but that's 20 because they follow the manufacturer's 21 instructions and don't do exactly what I do.</p> <p>22 In my patients, it's basically, 23 no, it doesn't happen.</p> <p>24 Could you have it happen? One</p>	<p>1 Let me -- is infection a risk 2 with surgery using Uretex and Desara?</p> <p>3 A. Yes.</p> <p>4 Q. Are urinary problems such as 5 urinary frequency, urgency, dysuria, 6 retention, obstruction and incontinence, are 7 those potential risks with Desara and Uretex?</p> <p>8 A. Yes.</p> <p>9 Q. Organ and nerve damage, are 10 those potential risks with Desara and Uretex?</p> <p>11 A. Yes.</p> <p>12 Q. Postoperative bleeding, is that 13 a potential risk with Uretex and Desara?</p> <p>14 A. Yes.</p> <p>15 Q. Wound complications, is that a 16 potential risk with Desara and Uretex?</p> <p>17 A. Yes.</p> <p>18 Q. Inflammation, is that a 19 potential risk?</p> <p>20 A. Yes.</p> <p>21 Q. Fistula formation, is that a 22 potential risk with Uretex and Desara?</p> <p>23 A. Yes.</p> <p>24 Q. Neuromuscular problems with the</p>

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<p>1 pelvic floor muscles, is that a potential</p> <p>2 risk with Uretex and Desara?</p> <p>3 A. Yes.</p> <p>4 Q. Lower extremity pain, is that a</p> <p>5 potential risk?</p> <p>6 A. No.</p> <p>7 Q. Abdominal pain, is that a</p> <p>8 potential risk?</p> <p>9 A. Yes.</p> <p>10 Q. Need for additional surgery, is</p> <p>11 that a potential risk with Uretex and Desara?</p> <p>12 A. Yes.</p> <p>13 Q. Failure of the procedure, is</p> <p>14 that a potential risk with Uretex and Desara?</p> <p>15 A. Yes.</p> <p>16 Q. Foreign body reaction is a</p> <p>17 potential risk, chronic foreign body reaction</p> <p>18 with Uretex and Desara?</p> <p>19 A. Yes.</p> <p>20 Q. Exposure or erosion or</p> <p>21 extrusion, is that a potential risk with</p> <p>22 Desara and Uretex?</p> <p>23 A. Yes. Again, all of those</p> <p>24 following the manufacturer's instructions for</p>	<p>1 understand them.</p> <p>2 Q. This is mesh that's been in the</p> <p>3 body?</p> <p>4 A. No. No. No.</p> <p>5 Q. Okay.</p> <p>6 A. Expired, donated from reps.</p> <p>7 Q. Okay. Have you seen any mesh,</p> <p>8 TVT® mesh, falling apart in the body?</p> <p>9 A. Yes. Yes.</p> <p>10 Q. In your explanting procedures?</p> <p>11 A. Yes.</p> <p>12 Q. And if I asked this, I</p> <p>13 apologize.</p> <p>14 Can you point me to any medical</p> <p>15 literature where someone has described a</p> <p>16 problem with the TVT® mesh falling apart as</p> <p>17 you describe it?</p> <p>18 A. You mean the fraying?</p> <p>19 Q. I mean, the falling -- you said</p> <p>20 that it falls apart.</p> <p>21 I want to know has anybody</p> <p>22 written a medical paper that has said, you</p> <p>23 know, this TVT® mesh falls apart when it gets</p> <p>24 in the body.</p>
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<p>1 implantation.</p> <p>2 Q. And contraction or shrinkage of</p> <p>3 tissues, is that a potential risk with Uretex</p> <p>4 and Desara?</p> <p>5 A. Yes.</p> <p>6 Q. All right. Now, do you have</p> <p>7 any opinion as to what the relative risks are</p> <p>8 of those things we went through for TVT®</p> <p>9 versus Uretex and Desara slings?</p> <p>10 A. Following the manufacturer's</p> <p>11 instructions?</p> <p>12 Q. Yes.</p> <p>13 A. Okay. They're slightly higher</p> <p>14 for TVT® because of the weave design of the</p> <p>15 mesh that upon any traction it frays and</p> <p>16 literally falls apart.</p> <p>17 Q. This falling apart, have you</p> <p>18 actually seen it fall apart?</p> <p>19 A. Oh, yes.</p> <p>20 Q. This is in your surgeries you</p> <p>21 do?</p> <p>22 A. No, I have samples of mesh that</p> <p>23 I've -- I acquired almost all the mesh</p> <p>24 samples I could possibly acquire to</p>	<p>1 Have you read that anywhere?</p> <p>2 A. I can't recall.</p> <p>3 Q. You can't point me to anything?</p> <p>4 A. I cannot at this time, no.</p> <p>5 Q. And it's certainly not in your</p> <p>6 report, true?</p> <p>7 A. No.</p> <p>8 Q. True?</p> <p>9 A. True.</p> <p>10 Q. So your only basis for saying</p> <p>11 that in the body the TVT® mesh frays so badly</p> <p>12 that it falls apart is what you've seen from</p> <p>13 your explant procedures, true?</p> <p>14 A. Yes.</p> <p>15 Q. Are there any samples of that</p> <p>16 in your report?</p> <p>17 A. No.</p> <p>18 Q. Do you have any -- if we want</p> <p>19 to say, I don't know, I've never seen such a</p> <p>20 thing, I've never heard of such a thing, we</p> <p>21 wanted to see it, what do you do?</p> <p>22 A. I have pictures.</p> <p>23 Q. You have pictures that aren't</p> <p>24 in your report?</p>

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<p>1 A. Yes.</p> <p>2 Q. Okay.</p> <p>3 A. Lots of pictures.</p> <p>4 Q. And these are -- this is mesh</p> <p>5 falling apart, not as a result of you taking</p> <p>6 it out?</p> <p>7 A. No.</p> <p>8 Q. Why do you think nobody else</p> <p>9 has ever written about that?</p> <p>10 A. I don't know. I haven't</p> <p>11 written about it.</p> <p>12 Q. Okay. So other than this</p> <p>13 tenancy -- and the reason you think it frays</p> <p>14 and falls apart is because the edge -- tell</p> <p>15 me why you think the TVT® frays and falls</p> <p>16 apart as you describe it and the other ones</p> <p>17 don't.</p> <p>18 A. It has to do with the weave.</p> <p>19 Q. Okay.</p> <p>20 A. So when TVT® was mechanically</p> <p>21 cut early on it was clear before they made it</p> <p>22 blue, it was harder to see it. But when it</p> <p>23 became blue, it became very visible in the</p> <p>24 tissues. I have a clear recollection from</p>	<p>1 that causes this fraying and falling apart</p> <p>2 problem is the way it's cut on the edges, is</p> <p>3 that what you're saying?</p> <p>4 A. Yes. And that's why it went to</p> <p>5 laser cut afterwards.</p> <p>6 Q. Does the laser cut have the</p> <p>7 same problem?</p> <p>8 A. To a less extent.</p> <p>9 Q. Okay. So is the laser-cut</p> <p>10 mesh, do the risks of that outweigh the</p> <p>11 benefits so that it never should have been</p> <p>12 put on the market?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. For what reason?</p> <p>15 A. It's the same thing. The</p> <p>16 elasticity. It still pops apart where the</p> <p>17 laser seals it a little bit, but if you put</p> <p>18 traction on it, it pops apart.</p> <p>19 Q. So the problem you have -- I've</p> <p>20 heard two problems you have with the mesh</p> <p>21 itself. We've talked about the</p> <p>22 instrumentation issue, and we've talked about</p> <p>23 the technique.</p> <p>24 A. Yes.</p>
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<p>1 years ago on a slide where I'm not removing</p> <p>2 the sling, but I'm fixing the woman's</p> <p>3 prolapse after she had her sling and have the</p> <p>4 vaginal wall open and you can see a hairpin</p> <p>5 loop of mesh attached in there.</p> <p>6 I probably wouldn't have seen</p> <p>7 that when it was clear. I did see it when it</p> <p>8 was clear when I first handled it early on.</p> <p>9 Q. So --</p> <p>10 A. So it has to do -- you know,</p> <p>11 this mesh starts as a suture, and then it</p> <p>12 goes through a machine that knits it into a</p> <p>13 big sheet, and then it gets cut.</p> <p>14 So TVT® and the Boston</p> <p>15 Scientific product are somewhat similar in</p> <p>16 the fact that when you first cut the TVT®</p> <p>17 early on when it was mechanically cut, the</p> <p>18 edges would fray. It was sort of like</p> <p>19 cutting a sweater that your grandma knit and</p> <p>20 you got a cut and it started to unfray, but</p> <p>21 it wasn't on the body like a sweater. It's a</p> <p>22 strip of mesh so when you cut it and you pull</p> <p>23 on it, they would pop off.</p> <p>24 Q. So the problem with the weave</p>	<p>1 Q. The mesh itself, what I've</p> <p>2 heard, is that you have two criticisms of the</p> <p>3 TVT® mesh: One is whether it's mechanically</p> <p>4 cut or laser cut, the edges are -- or the</p> <p>5 weave and the edges are susceptible to</p> <p>6 fraying and falling apart in the body, that's</p> <p>7 one, right?</p> <p>8 A. Yes.</p> <p>9 Q. And then number two, the pores,</p> <p>10 once they're in the body, are not big enough</p> <p>11 to allow the tissue ingrowth?</p> <p>12 A. Yes.</p> <p>13 And three, and this applies to</p> <p>14 all polypropylene, including the</p> <p>15 polypropylene I'm implanting, was not very</p> <p>16 clear when this all came out, when this</p> <p>17 product first came out, that polypropylene</p> <p>18 degrades.</p> <p>19 Q. Now, are you aware of any</p> <p>20 medical literature where someone has</p> <p>21 identified degradation of TVT® polypropylene</p> <p>22 as causing clinical problems for patients?</p> <p>23 A. Well, the Clavé study looked at</p> <p>24 polypropylene TVT® and studied that that</p>

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<p>1 causes contraction and fibro -- a chronic</p> <p>2 inflammation and scarring and shortening and</p> <p>3 shrinkage and possibly erosion.</p> <p>4 Q. So your interpretation of the</p> <p>5 Clavé paper is that it says that degradation</p> <p>6 of TVT® polypropylene produces clinical</p> <p>7 problems for patients?</p> <p>8 A. Yes.</p> <p>9 Q. All right. Any other paper</p> <p>10 besides that?</p> <p>11 A. With TVT®?</p> <p>12 Q. Yes.</p> <p>13 A. Not that I recall off the top</p> <p>14 of my head.</p> <p>15 Q. Okay. Now I'm going to broaden</p> <p>16 it. You anticipated that.</p> <p>17 Are you aware of any papers</p> <p>18 that say polypropylene in general in use with</p> <p>19 vaginal surgery degrades to such an extent</p> <p>20 that it causes clinical problems for</p> <p>21 patients?</p> <p>22 A. All mesh, or mesh in general,</p> <p>23 right?</p> <p>24 Q. Yes.</p>	<p>1 complications?</p> <p>2 A. Yes.</p> <p>3 Q. Potential complications?</p> <p>4 A. Yes.</p> <p>5 Q. Which ones?</p> <p>6 A. Cording, roping, because of the</p> <p>7 fraying that occurs and loss of fibers.</p> <p>8 Q. Okay. And then what</p> <p>9 complication does that cause for the patient?</p> <p>10 A. Retention. It can cause pelvic</p> <p>11 pain. It can cause exposure, erosion.</p> <p>12 Q. Okay. Do you have an opinion</p> <p>13 as to whether the rate of exposure and</p> <p>14 erosion with TVT® is higher or lower or the</p> <p>15 same as compared to Uretex and Desara?</p> <p>16 A. I don't see many patients that</p> <p>17 have a Desara problem. I see very few</p> <p>18 patients that have a Uretex problem. I do</p> <p>19 see many patients with TVT® problem.</p> <p>20 Q. Do you have any notion as to</p> <p>21 how many TVT®s have been implanted versus</p> <p>22 Desara and Uretex?</p> <p>23 A. I'm sure there's a lot more</p> <p>24 TVT®s.</p>
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<p>1 A. Yeah.</p> <p>2 I am. Let me refresh my</p> <p>3 memory.</p> <p>4 Q. Let me ask this.</p> <p>5 A. Yes.</p> <p>6 Q. Do you cite any paper in either</p> <p>7 of your reports, Exhibits 2 or 3, concerning</p> <p>8 TVT® or Gynemesh® that to support the</p> <p>9 proposition that polypropylene degrades and</p> <p>10 causes clinical problems for patients?</p> <p>11 A. I don't know that there's any</p> <p>12 papers that say there's clinical problems.</p> <p>13 Q. Okay. Now, by the way, how</p> <p>14 many hours did you spend just preparing for</p> <p>15 this deposition?</p> <p>16 A. 20.</p> <p>17 Q. Okay. We went through a long</p> <p>18 list of potential risks of sling surgery</p> <p>19 using polypropylene, right?</p> <p>20 Remember we compared -- or we</p> <p>21 talked about Uretex and Desara and all of the</p> <p>22 risks they have.</p> <p>23 Does TVT® have a greater risk</p> <p>24 than Desara or Uretex with respect to any</p>	<p>1 Q. Right.</p> <p>2 So it's not really fair to</p> <p>3 compare numbers of problems you see with</p> <p>4 Desara and Uretex versus TVT®, true?</p> <p>5 A. Sure. Yes.</p> <p>6 Q. Okay. Are you aware of any</p> <p>7 study that says that TVT® with respect to any</p> <p>8 of the complications of -- the potential</p> <p>9 complications of SUI surgery with mesh has a</p> <p>10 greater propensity for any of these</p> <p>11 calculations than competitor products?</p> <p>12 A. That study hasn't been done.</p> <p>13 Q. And do you have an opinion --</p> <p>14 do you believe you have sufficient</p> <p>15 information to state an opinion as to the</p> <p>16 comparative risks of TVT® versus Uretex and</p> <p>17 Desara with respect to any of these</p> <p>18 complications?</p> <p>19 A. My opinion is based on the</p> <p>20 number of patients I see with complications</p> <p>21 with all slings. And TVT® is much higher</p> <p>22 than the others.</p> <p>23 Q. Okay. But you also have just</p> <p>24 agreed that there are far -- there have been</p>

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<p>1 far more TVT@s implanted in the population</p> <p>2 than there have been Desara and Uretex, true?</p> <p>3 A. Yes.</p> <p>4 Q. Okay. 10 or 20 times as many,</p> <p>5 right?</p> <p>6 A. I wouldn't know.</p> <p>7 Q. Okay. So do you believe you</p> <p>8 have a valid scientific basis to state that</p> <p>9 the complications with TVT® are greater than</p> <p>10 Uretex and Desara?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. And what is that</p> <p>13 scientific basis?</p> <p>14 A. It's based on my entire</p> <p>15 knowledge, my training, my expertise as a</p> <p>16 vaginal surgeon, the review of all of the</p> <p>17 materials that I've had to review, reading as</p> <p>18 much literature as possible. There are very</p> <p>19 few papers that talk about complications from</p> <p>20 slings, and there's very few papers, if any,</p> <p>21 that compare one sling over the other for</p> <p>22 complications.</p> <p>23 Q. Well, if there's very few</p> <p>24 papers, how can that be a scientific basis?</p>	<p>1 wasn't clear, and I'll make it.</p> <p>2 Can you point me to any</p> <p>3 scientific literature that says in the body</p> <p>4 TVT® has more risk of complications than</p> <p>5 Uretex or Desara or any other type of</p> <p>6 polypropylene sling?</p> <p>7 A. Not at this time.</p> <p>8 Q. Okay. Do you have any -- and I</p> <p>9 think -- do you have any estimate as to what</p> <p>10 percentage of patients with TVT® slings have</p> <p>11 had problems with long-term inflammation?</p> <p>12 A. Ask this again, please.</p> <p>13 Q. Do you have any -- and I</p> <p>14 think -- let me just ask a global question.</p> <p>15 You list in your report at</p> <p>16 page 5 -- okay, let's go to your report, your</p> <p>17 TVT® report, page 5.</p> <p>18 Okay. Paragraph A, under the</p> <p>19 list of opinions, right?</p> <p>20 A. Yes.</p> <p>21 Q. And you see you say the mesh in</p> <p>22 TVT® can cause foreign body reaction,</p> <p>23 inflammation, et cetera.</p> <p>24 Do you see that?</p>
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<p>1 I guess that's my problem.</p> <p>2 I understand that you in your</p> <p>3 practice have seen more TVT® complications</p> <p>4 than Desara and Uretex. I understand that.</p> <p>5 Okay. But you've just said there's a whole</p> <p>6 lot more TVT@s out in the market.</p> <p>7 So can you point me to any</p> <p>8 specific -- I don't mean general, my training</p> <p>9 and experience. Can you point me to any</p> <p>10 specific scientific basis that you have for</p> <p>11 stating the opinion that TVT® has a greater</p> <p>12 risk of complications than Desara or Uretex?</p> <p>13 A. There's scientific evidence</p> <p>14 that looks at what happens to the different</p> <p>15 meshes with force.</p> <p>16 Q. Okay. What is that?</p> <p>17 A. I am sorry.</p> <p>18 Q. What is that scientific</p> <p>19 evidence?</p> <p>20 A. That is a paper that I believe</p> <p>21 was done by Wylie to put force on multiple</p> <p>22 different slings and look at the way these</p> <p>23 properties behave outside of the body.</p> <p>24 Q. So do you have any -- and I</p>	<p>1 A. Yes.</p> <p>2 Q. Okay. Do you have any opinion</p> <p>3 as to what percentage of the patients who</p> <p>4 have had a TVT® implanted have problems of</p> <p>5 chronic foreign body reaction, inflammation,</p> <p>6 fibrotic bridging, mesh contraction, fraying,</p> <p>7 particle loss?</p> <p>8 A. All of the patients I see in my</p> <p>9 practice.</p> <p>10 Q. In your explant practice?</p> <p>11 A. Yes.</p> <p>12 Q. I appreciate that, but my</p> <p>13 question was of all of the people that have</p> <p>14 had them implanted, do you have an opinion as</p> <p>15 to what percentage have had any of those</p> <p>16 problems?</p> <p>17 A. I don't.</p> <p>18 Q. Okay.</p> <p>19 A. I have a guesstimate.</p> <p>20 Q. I'll hear it even though I</p> <p>21 don't think it's admissible, but go ahead.</p> <p>22 A. 30 percent.</p> <p>23 Q. And what's that based on?</p> <p>24 A. On the shrinkage rate of the</p>

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<p>1 polypropylene mesh that it shrinks 20 to 2 40 percent. So about 30. So about 3 30 percent of those patients are going to 4 have a problem. 5 Q. What's that 20 to 40 percent 6 shrinkage rate based on? 7 Is that in vivo or ex vivo? 8 A. Well, in vivo in animals. It's 9 not in vivo in patients. 10 Q. So do you have any data that 11 talks about the shrinkage rate of mesh, of a 12 TVT® mesh, in a woman? 13 A. No. 14 Q. And a woman can have foreign 15 body reaction and have no symptoms, true? 16 A. Some might, yes. 17 Q. A woman can have fibrotic 18 bridging and have no symptoms, true? 19 A. I haven't seen any. 20 Q. I didn't ask whether you've 21 seen any. 22 Can that occur? 23 A. I haven't seen everyone. I 24 want to be truthful and precise, but just as</p>	<p>1 not -- it's not very precise. 2 Q. Did you read the IFU before you 3 implanted the TVT® a number of years ago? 4 A. Yes. 5 Q. Do you believe that experienced 6 surgeons who perform SUI surgery with mesh in 7 2010 and before were aware that a potential 8 complication was acute or chronic pain? 9 A. I don't think they knew about 10 it, no. 11 Q. What about acute or chronic 12 pain with intercourse? 13 A. No, I don't think they knew 14 about it. 15 Q. So you don't think experienced 16 surgeons before 2010 knew that acute or 17 chronic pain with intercourse was a possible 18 complication with mesh SUI surgery? 19 A. May I ask what would you call 20 an experienced surgeon? 21 Q. Somebody that does sling 22 surgery on a regular basis. 23 A. I don't know what a regular 24 basis -- once a week?</p>
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<p>1 I don't know -- 2 Q. Well, there's varying degrees 3 of fibrotic bridging, aren't there? 4 A. I think fibrotic bridging is 5 fibrotic bridging. If it comes together as 6 granulomas, it's granulomas. 7 Q. Are there varying degrees of 8 mesh contracture? 9 A. It can vary, 20, 30, 40 10 percent. 11 Q. Down here in opinion C, Ethicon 12 failed to adequately describe to physicians 13 how to properly tension the TVT®. 14 Does this go back to the 15 technique criticisms you had? 16 A. That's actually in the IFU. In 17 the IFU in one place it says, "minimal 18 tension," and in one place it says, "no 19 tension." It talks about doing the placement 20 under a local or under a general. Under 21 local at 300 MLs they're supposed to cough 22 until there's a drop. So that is a 23 tensioning approach. But later on they say, 24 "no tension" and "minimal tension." So it's</p>	<p>1 Q. You can't answer the question? 2 A. No. I'm trying to ascertain 3 what a -- I don't think an experienced 4 surgeon is someone who does one a week. I 5 think an experienced surgeon would be someone 6 who does three, four a week. And even I, 7 when I was first learning about these slings, 8 wouldn't have thought that a patient would 9 have had pain with intercourse from a 10 polypropylene sling. 11 And I saw many patients that 12 went to their doctors and all they heard was 13 a common phrase, "It's not the mesh, it's not 14 the mesh, it's not the mesh." So the 15 examination has to be very specific and 16 precise on where the mesh is placed. And 17 when you do that and you listen to these 18 women, you see that that is the cause, 19 confirmed by my own removal and their pain 20 goes away. 21 Q. Was pain with intercourse a 22 risk with Mersilene? 23 A. I didn't think it was. 24 Q. Is it?</p>

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<p>1 A. Knowing what I know today, 2 probably. But it's a lot softer. It's 3 lightweight. It's 33 grams per meter 4 squared. It's not 100. This lays very flat. 5 You can't feel it so it drastically less. 6 Q. Is pain with intercourse a risk 7 with the Burch procedure or the MMK 8 procedure? 9 A. No. 10 Q. Paragraph E, Ethicon failed to 11 inform physicians of certain patient 12 populations may be more prone to experience 13 adverse outcomes or higher frequency or 14 severity of risk. 15 What patient populations fall 16 into that category? 17 A. Patients that have excessive 18 scarring, and you don't know who that is, but 19 there are patients that formed keloids, for 20 example. 21 The only warning is in patients 22 that are growing or pregnant are going to 23 have a delivery. So patients that are on 24 steroids, patients who are diabetic, women</p>	<p>1 along, it changed the mindset of everyone. 2 You don't need to harvest. You don't need to 3 take the extra time in the OR. This is quick 4 and easy. Here you go. It's a whole kit; 5 put it in. The report by Ulmsten was you 6 could do this in 25 minutes under local. The 7 patient goes home the same day. It all 8 sounded really, really good, and a lot of 9 people abandoned doing autologous slings. 10 Q. As far as you understand, the 11 Desara sling is safe? 12 A. The way I use it, yes. 13 Q. It's not safe if you follow 14 manufacturer's instructions? 15 A. No. 16 Q. And the Uretex sling was safe 17 in your technique, but not using 18 manufacturer's instructions? 19 A. Correct. 20 Q. Okay. So down here in 21 paragraph F where you say that there were 22 safer alternative options available, what 23 available options were safer? 24 A. Burch, autologous slings,</p>
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<p>1 that have chronic obstructive lung disease, 2 elderly women that may not heal right. A 3 certain percentage of smokers. 4 Q. Those are all ones that should 5 not have -- 6 A. Those are ones that ought to be 7 warned that they may have a higher frequency 8 of complications. 9 Q. Autologous and cadaveric 10 slings, have they always been available for 11 SUI? 12 A. Autologous sling was actually 13 described in 1907 by Von Giordano was 14 actually an autologous sling. 15 Q. Yeah, I don't want to go back 16 quite that far. 17 Have they been in regular use 18 for how long? 19 A. I think they were really 20 popularized in the '40s by Aldridge. 21 Q. So in the 2000s, were doctors 22 regularly performing sling procedures with 23 cadavers and autologous grafts? 24 A. I think that when TVT® came</p>	<p>1 cadaveric slings. 2 Q. Do you still offer patients 3 Burch as an alternative if you're not going 4 to be doing an abdominal surgery? 5 A. I do. 6 Q. Has anyone chosen that? 7 A. One patient. 8 Q. So as you're sitting here 9 today, do you believe a Burch procedure is a 10 safer procedure for a patient than any type 11 of mesh sling procedure? 12 A. Long term, yes. 13 Q. Okay. And do you believe 14 autologous and cadaveric slings are safer 15 procedures than any kind of mesh? 16 A. Yes. 17 Q. Do you tell your patients that, 18 do you tell your patients that long -- when 19 you're having this discussion with them and 20 giving the alternatives, do you tell your 21 patients that you can either have a mesh 22 sling, or you can have an autologous sling, 23 or you can have a cadaveric sling, or you can 24 have a Burch procedure?</p>

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<p>1 Those are your four 2 alternatives, right? 3 Is that right? 4 A. And some urethral plication. 5 Q. And what is that, briefly? 6 A. Briefly, it's the pubourethral 7 ligaments that are replaced by TVT®, which is 8 the theory of Ulmsten and Papa Petros. 9 Instead of replacing them with an implant, 10 you grasp them and you suture them underneath 11 the midline and create a in-situ sling. 12 Q. So it's kind of a native tissue 13 repair, so to speak? 14 A. You could call it that, yes. 15 Q. It's not using any kind of 16 outside material? 17 A. Correct. 18 Q. Okay. So that's the fifth one 19 you offer? 20 A. Yes, if their urodynamics are 21 not severe incontinence. 22 Q. And do you believe that's a 23 safer alternative than any type of mesh? 24 A. That is the safest, yes.</p>	<p>1 SUI, all these other procedures, are safer 2 than any type of mesh sling? 3 A. No, there's literature that 4 says there's alternatives. I don't know that 5 anyone has done a head-to-head comparison 6 long term for these procedures the way that 7 they do surgery. 8 When I'm counseling my 9 patients, it's the way that I do surgery and 10 even the polypropylene slings that I place, I 11 do differently. 12 Q. My question is are you aware of 13 any literature, scientific, published 14 literature, that says that mesh slings are 15 the least a safe alternative for SUI surgery 16 long term? 17 A. No. 18 Q. Okay. In fact, are you a 19 member of any organizations? 20 A. Yes. 21 Q. What? 22 A. ACOG, Society of Gynecologic 23 Surgeons, AUGS, AAGL. 24 Q. Do any of those organizations</p>
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<p>1 Q. Okay. So when you're sitting 2 there talking to a patient and you're giving 3 them these five alternatives, do you tell 4 them that all of the alternatives are safer 5 long term than a mesh procedure? 6 A. I tell them that I don't know 7 what the long-term complications from a sling 8 are going to be. I tell them that there's a 9 failure from the native tissue repair, that 10 the Burch procedure is more invasive, that 11 the harvesting a piece of their own body is a 12 little invasive, but it's not terribly 13 invasive. A Burch is more invasive than a 14 sling, and that a cadaveric sling is the same 15 sequence of steps as putting in a 16 polypropylene sling. 17 And I let them pick. 18 Q. And then do you tell them that 19 long term all the alternatives, other than a 20 mesh sling, are safer? 21 A. Yes. 22 Q. Okay. Is there literature that 23 you can point me to, reliable scientific 24 literature, that says that all procedures for</p>	<p>1 publish guidelines or practice parameters or 2 position statements about SUI surgery? 3 A. I think AUGS and SUFU has put 4 something out there. 5 Q. And do either of those 6 publications state that mesh surgery is the 7 gold standard for SUI treatment? 8 A. They do call it the gold 9 standard. 10 Q. What does the gold standard 11 mean to you? 12 A. What it means to me is if you 13 take a group of surgeons that do the same 14 procedure, that they have uniform results and 15 uniform complications. That's what the gold 16 standard means to me. 17 Q. It doesn't mean it's the 18 preferred procedure? 19 A. I think that the way that it's 20 used it implies that, but that's not what it 21 means to me. 22 Q. So the gold standard to you, if 23 it's published in these position statements 24 by these organizations that you're a member</p>

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<p>1 of, does not mean that it's the preferred 2 procedure?</p> <p>3 A. That's not what it means to me. 4 I've seen -- I remember looking at that and 5 calling it the gold standard and years ago 6 the Burch was the gold standard and the 7 sacrocolpopexy is the gold standard. And 8 what I've always taken that to mean is when 9 we treat women across the country, across the 10 planet, that the procedures that we do in the 11 hands of many are safe, which is what this 12 data is supposed to extrapolate and tell us, 13 the risk/benefit ratio. So that if someone 14 who is a very good scientist does a very 15 well-designed study and comes up with a 16 percentage of cure, that that would then 17 extrapolate to the hands of other surgeons.</p> <p>18 Q. Do you believe that mesh sling 19 surgery is the gold standard for the 20 treatment of SUI?</p> <p>21 A. I believe slings are the gold 22 standard.</p> <p>23 Q. That wasn't my question.</p> <p>24 A. I know.</p>	<p>1 A. It says that, yes.</p> <p>2 Q. And number two, do you agree 3 with that statement?</p> <p>4 A. I do not.</p> <p>5 Q. And because?</p> <p>6 A. Because they're talking about 7 two completely different types of midurethral 8 slings. So first is the retropubic TVT®, and 9 the second is the TOT. So if you lump those 10 two together, those are completely different 11 slings even though they're multi-incision. 12 They have a completely different set of cure 13 and complication profiles.</p> <p>14 Q. And you believe that the 15 obturator slings are less safe than the 16 retropubic?</p> <p>17 A. If we define -- how do we 18 define safe? Bladder perforation, they have 19 less bladder perforations. They have --</p> <p>20 Q. Overall safety.</p> <p>21 A. Overall safety?</p> <p>22 Q. And efficacy.</p> <p>23 A. They are less efficacious.</p> <p>24 They're safer in the sense that you don't</p>
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<p>1 Q. My question is do you believe 2 that mesh slings are the gold standard for -- 3 well, strike that.</p> <p>4 The AUGS does say that mesh 5 slings are the gold standard for treatment of 6 SUI, true?</p> <p>7 A. It says, if I can be specific, 8 multi-incision slings. So there's 9 single-incision slings. Those aren't really 10 included.</p> <p>11 Q. And the TVT® is not a single 12 incision?</p> <p>13 A. It's not a single-incision 14 sling.</p> <p>15 Q. Do you agree that the AUGS says 16 that multi-incision polypropylene slings are 17 the gold standard for treatment of SUI?</p> <p>18 A. And I'm going to answer that 19 question in, no, I don't believe it's the 20 gold standard.</p> <p>21 Q. First of all, it's a two-part 22 question.</p> <p>23 First of all, do you agree 24 that's what the AUGS says?</p>	<p>1 enter the pelvic bowl and you injure 2 structures, but they have their own unique 3 set of problems with the leg pain, as you 4 mentioned in one of your questions, with limb 5 pain as it transverses the obturator muscles 6 and the adductors.</p> <p>7 So they lump those two 8 different kinds of slings as midurethral 9 slings, but they're separate and distinct 10 beasts.</p> <p>11 Q. A retropubic midurethral 12 polypropylene sling, is that the gold 13 standard as far as you're concerned for the 14 treatment of SUI?</p> <p>15 A. I think the gold standard is 16 being able to do a sling. That's what really 17 works.</p> <p>18 Q. But again --</p> <p>19 A. Can it be out of polypropylene 20 done a very specific way like I do? Yes.</p> <p>21 But the way that the gold 22 standard is set in that statement it's using 23 the manufacturer's instructions, and I don't 24 think that those slings are the gold standard</p>

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<p>1 being placed the way that the company</p> <p>2 suggested it be placed.</p> <p>3 Q. Do you classify the TVT® mesh</p> <p>4 pore size as macroporous or microporous?</p> <p>5 A. It's less than 1 millimeter, so</p> <p>6 it's micro.</p> <p>7 Q. In the body or outside the</p> <p>8 body?</p> <p>9 A. Inside the body.</p> <p>10 Q. Okay. So under the Amid</p> <p>11 classification, are the measurements made</p> <p>12 inside of the body or outside the</p> <p>13 classification?</p> <p>14 A. Amid classification is 75</p> <p>15 microns. Everything is macroporous by that</p> <p>16 definition.</p> <p>17 Q. So are you aware of any</p> <p>18 classification system other than the Amid</p> <p>19 system for classifying pore size in mesh?</p> <p>20 A. No.</p> <p>21 Q. All right. Under that</p> <p>22 classification, the mesh in TVT® is</p> <p>23 macroporous?</p> <p>24 A. Yes.</p>	<p>1 often talk about mechanically cut mesh can</p> <p>2 fray, et cetera, and release particles.</p> <p>3 Do you have anywhere in your</p> <p>4 report that you refer to laser-cut mesh</p> <p>5 having that same issue?</p> <p>6 A. Which issue was that? The</p> <p>7 fraying?</p> <p>8 Q. Like on page 9 you say the</p> <p>9 mechanically cut mesh was known to rope, curl</p> <p>10 and deform, and the mechanically cut version</p> <p>11 of mesh could fray or release particles.</p> <p>12 Do you have anywhere in your</p> <p>13 report where you say laser-cut mesh can rope,</p> <p>14 curl or deform or release particles?</p> <p>15 A. Well, I didn't specifically</p> <p>16 state that, but it's implied.</p> <p>17 Q. How is it implied?</p> <p>18 A. Well, just because it's laser</p> <p>19 cut doesn't mean it's not going to fray.</p> <p>20 Q. Do you say that in here</p> <p>21 anywhere?</p> <p>22 I see where you specifically</p> <p>23 say the mechanically cut mesh will fray and</p> <p>24 have particle loss, et cetera.</p>
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<p>1 Q. Right?</p> <p>2 Okay. How did you decide which</p> <p>3 Ethicon testimony to cite in your report and</p> <p>4 which Ethicon documents to cite in your</p> <p>5 report?</p> <p>6 Let me back up. First of all,</p> <p>7 are you aware that there have been thousands</p> <p>8 of pages of testimony from Ethicon employees?</p> <p>9 A. I would believe so.</p> <p>10 Q. There would be millions of</p> <p>11 pages produced from Ethicon?</p> <p>12 A. I wouldn't doubt it.</p> <p>13 Q. And in your report, you cited a</p> <p>14 few pieces of testimony and cited several</p> <p>15 documents, right?</p> <p>16 A. Yes.</p> <p>17 Q. How did you decide which pieces</p> <p>18 of testimony to cite and what not to cite and</p> <p>19 which documents to cite and what not to cite?</p> <p>20 A. I cited every -- I gathered</p> <p>21 everything that I thought was relevant from</p> <p>22 what was sent to me and cited it.</p> <p>23 Q. Do you say anywhere in your</p> <p>24 report that laser-cut mesh -- I see where you</p>	<p>1 Did you ever say laser-cut mesh</p> <p>2 will do that?</p> <p>3 A. I may have been remiss in</p> <p>4 saying that.</p> <p>5 Q. You mean in not saying that?</p> <p>6 A. Not saying that, yes.</p> <p>7 Q. When you take a -- when you</p> <p>8 explant a TVT®, are you able to tell whether</p> <p>9 it is laser cut or mechanically cut?</p> <p>10 A. I can tell before because I</p> <p>11 have the implant log.</p> <p>12 Q. Does the implant log specify</p> <p>13 mechanical cut versus laser cut?</p> <p>14 A. It does.</p> <p>15 Q. It says it on there?</p> <p>16 A. Uh-huh. 810081 BL.</p> <p>17 Q. That's the part number or</p> <p>18 whatever?</p> <p>19 A. Yes. I am sorry, 41. 810041.</p> <p>20 The 81 is the TOT.</p> <p>21 Q. I think you mentioned 34 TVT®s</p> <p>22 you removed last year?</p> <p>23 A. Yes.</p> <p>24 Q. Were you including all the</p>

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<p>1 TVT®s or just the TVT® that's the subject of</p> <p>2 your report here?</p> <p>3 A. Just the subject of my report.</p> <p>4 Q. So TVT-Os and Abbrevos and</p> <p>5 whatever else would be on top of that?</p> <p>6 A. That's different, yes.</p> <p>7 Q. Of that 34, can you tell how</p> <p>8 many were mechanically cut and how many laser</p> <p>9 cut?</p> <p>10 A. Yes, but I didn't separate them</p> <p>11 out.</p> <p>12 Q. But just so we're clear, is it</p> <p>13 your testimony that the laser-cut mesh never</p> <p>14 should have been sold either?</p> <p>15 A. Yes.</p> <p>16 Q. The Desara and Uretex, were</p> <p>17 those laser cut or mechanically cut?</p> <p>18 A. They're not -- they're neither.</p> <p>19 Q. Okay. And do you ever have to</p> <p>20 cut a Desara to create exposed edges, a</p> <p>21 Desara and a Uretex?</p> <p>22 A. No, just after implantation,</p> <p>23 the part that is above the skin, that's the</p> <p>24 only cut.</p>	<p>1 its configured design. It's a design flaw.</p> <p>2 It should not do that. There's other meshes</p> <p>3 that don't do that.</p> <p>4 Q. I'm talking about particle</p> <p>5 loss. I'm not talking about fraying now.</p> <p>6 Okay. I'm talking about</p> <p>7 particles actually breaking off.</p> <p>8 Is that what you mean by</p> <p>9 particle loss?</p> <p>10 A. Well, they're almost one in the</p> <p>11 same.</p> <p>12 The reason the particles break</p> <p>13 off and they fray is because the actual weave</p> <p>14 design of the mesh is flawed. And because</p> <p>15 it's flawed, when you put traction on it, the</p> <p>16 actual heat -- however they weave this, the</p> <p>17 curly Q breaks off. That loses that</p> <p>18 attachment holding the two sutures together,</p> <p>19 and it frays.</p> <p>20 Q. So do you believe there are</p> <p>21 situations where actual particles of the mesh</p> <p>22 separate from the body of the mesh?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. Have you seen that?</p>
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<p>1 Q. Can you point me to any</p> <p>2 scientific literature that says that particle</p> <p>3 loss with mesh causes any clinical problems</p> <p>4 for patients?</p> <p>5 A. No.</p> <p>6 Q. Have you ever written in any</p> <p>7 medical operative report or medical record</p> <p>8 for any patient that you believe some of</p> <p>9 their clinical problems were related to</p> <p>10 particle loss from mesh?</p> <p>11 A. Not in those words, no.</p> <p>12 Q. Have you ever referred to</p> <p>13 particle loss in any way in any medical</p> <p>14 record for any patient?</p> <p>15 A. Not at this time.</p> <p>16 Q. In fact, do you know whether</p> <p>17 particle loss from TVT® mesh causes any</p> <p>18 clinical problems with patients?</p> <p>19 A. I do.</p> <p>20 Q. Okay. What's your basis for</p> <p>21 that?</p> <p>22 A. It narrows the caliber, the</p> <p>23 diameter of the mesh, because the actual</p> <p>24 weave unravels. When it unravels, it loses</p>	<p>1 A. Yes.</p> <p>2 Q. And has it ever -- well, I've</p> <p>3 already asked that question.</p> <p>4 A. It's the only sling that does</p> <p>5 this. The other slings don't behave this way</p> <p>6 at all.</p> <p>7 MR. MATTHEWS: Break time?</p> <p>8 MR. BALL: Sure. Can I ask one</p> <p>9 more question before we break?</p> <p>10 MR. MATTHEWS: Sure.</p> <p>11 QUESTIONS BY MR. BALL:</p> <p>12 Q. Can you point me to anybody</p> <p>13 else who has written a peer-reviewed medical</p> <p>14 paper that says TVT® has all of these</p> <p>15 problems with fraying and that type of thing</p> <p>16 that the other meshes don't have, like you</p> <p>17 just said?</p> <p>18 Can you point me to anybody</p> <p>19 that has published something and agrees with</p> <p>20 that?</p> <p>21 A. I don't think that they've</p> <p>22 compared it to other slings.</p> <p>23 Q. So you can't point me to any</p> <p>24 paper that agrees with that statement you've</p>

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<p>1 made, true?</p> <p>2 A. Not at this time.</p> <p>3 Q. True?</p> <p>4 A. Yes.</p> <p>5 MR. BALL: Okay. That's it.</p> <p>6 We'll take a break.</p> <p>7 (Off the record at 11:08 a.m.)</p> <p>8 QUESTIONS BY MR. BALL:</p> <p>9 Q. Now, have you ever -- let me</p> <p>10 get to your CV here. You want to get that</p> <p>11 out. I've got just a few questions about</p> <p>12 that.</p> <p>13 It's attached, I think, to the</p> <p>14 back of -- have you ever published anything</p> <p>15 specifically about TVT®?</p> <p>16 A. No.</p> <p>17 Q. Have you ever published</p> <p>18 anything specifically about Gynemesh® PS?</p> <p>19 A. No.</p> <p>20 Q. Have you published anything</p> <p>21 about use of mesh in SUI surgery?</p> <p>22 A. I published a paper looking at</p> <p>23 the recommendation of a sling with SUI</p> <p>24 diagnosis.</p>	<p>1 A. No.</p> <p>2 Q. Have you ever said that to any</p> <p>3 group of doctors about Gynemesh® PS?</p> <p>4 A. No.</p> <p>5 Q. Why not?</p> <p>6 A. Don't normally get in front of</p> <p>7 a group of doctors.</p> <p>8 Q. Well, I mean, you've presented</p> <p>9 abstracts five times in the last five years,</p> <p>10 right, according to your presented abstracts</p> <p>11 in your CV?</p> <p>12 A. Which abstracts are you --</p> <p>13 Q. Looking at part of your résumé</p> <p>14 or your CV that says "Presented Abstracts."</p> <p>15 The second page of your CV.</p> <p>16 A. So that first one was</p> <p>17 sacrocolpopexy.</p> <p>18 Q. No. What I'm asking, did you</p> <p>19 actually go out there and present your</p> <p>20 abstract?</p> <p>21 A. I did not present it.</p> <p>22 Q. On any of these first five that</p> <p>23 were 2011 to the present, did you do the</p> <p>24 presentation?</p>
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<p>1 Q. Where was that published, or</p> <p>2 how long ago was that, let me ask that?</p> <p>3 A. '95.</p> <p>4 Q. Have you ever published that</p> <p>5 TVT® has all these problems and, therefore,</p> <p>6 should never have been sold?</p> <p>7 A. No.</p> <p>8 Q. Why not?</p> <p>9 A. I've been busy taking care of</p> <p>10 people.</p> <p>11 Q. Have you ever published that</p> <p>12 Gynemesh® PS -- strike that. Let me back up.</p> <p>13 Do you believe Gynemesh® PS was</p> <p>14 so poorly designed it never should have been</p> <p>15 sold?</p> <p>16 A. Yes.</p> <p>17 Q. Have you ever published that</p> <p>18 opinion?</p> <p>19 A. No.</p> <p>20 Q. Same reason?</p> <p>21 A. Yes.</p> <p>22 Q. Have you ever stated in any</p> <p>23 kind of presentation to other doctors that</p> <p>24 TVT® never should have been sold?</p>	<p>1 A. I did not.</p> <p>2 Q. Okay. So one of them is mesh</p> <p>3 complications requiring removal of</p> <p>4 midurethral slings, oral presentation.</p> <p>5 Did you do that?</p> <p>6 A. Did not.</p> <p>7 Q. Did you participate in whatever</p> <p>8 the materials were?</p> <p>9 A. Yes.</p> <p>10 Q. Do you have those?</p> <p>11 A. What do you mean by materials?</p> <p>12 Q. I assume when you make -- what</p> <p>13 was the format of this oral presentation?</p> <p>14 Let me back up. Why would you</p> <p>15 be listed as giving an oral presentation in</p> <p>16 September of 2011 about mesh complications</p> <p>17 requiring removal of midurethral slings, if</p> <p>18 you didn't do it?</p> <p>19 A. I did do it. I was part of the</p> <p>20 project, but I was not the one verbally</p> <p>21 presenting the project.</p> <p>22 Q. Were you there?</p> <p>23 A. No.</p> <p>24 Q. Okay. So what was the project?</p>

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<p>1 A. The project was looking at all 2 the slings that had issues. It didn't single 3 out TVT® at that time. 4 Q. Was that published in some 5 manner? 6 A. No. 7 Q. Were there slides or anything 8 to accompany this oral presentation? 9 A. I'm sure there were. 10 Q. Okay. Do you have those? 11 A. No. 12 Q. When did you decide that TVT® 13 was so unsafe and never should have been 14 sold? 15 A. Few years after it came out. 16 Q. Okay. So 2005 or before? 17 A. Around that time. 18 Q. So what about these invited -- 19 here's an invited lecture, Perils for removal 20 of mesh, roundtable discussion, did you 21 attend that? 22 A. That, I did. 23 Q. Are there any materials from 24 that?</p>	<p>1 discussions did you say that TVT® or 2 Gynemesh® PS should never be used, true? 3 A. True. 4 Q. And there's no written 5 materials for those roundtable discussions? 6 A. There was not. 7 Q. Now, do you have some role with 8 training people, residents? 9 A. Yes, I do. 10 Q. Where is that done? 11 A. That's at Mercy. 12 Q. How many do you train per year 13 or however it works? 14 A. The program is accredited for 15 six residents at each level for four years, 16 total of 24. 17 Q. So at any one time you're 18 dealing with 24? 19 A. There's 24 residents there. 20 It's one-on-one mostly when I'm dealing with 21 them. 22 Q. But do you deal with all 24 of 23 them throughout the course of the year? 24 A. Yeah.</p>
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<p>1 A. No, that was simply a 2 roundtable discussion. 3 Q. And at that roundtable 4 discussion, did you say either Gynemesh® PS 5 or TVT® was so unsafe it never should have 6 been sold? 7 A. I didn't single out any 8 manufacturer or any implant. The talk was 9 designed at helping docs manage patients that 10 had mesh complications. 11 Q. The same thing with the 12 April 2013 roundtable in Charleston? 13 A. Yes. 14 Q. So you have had occasions where 15 you've made presentations about mesh 16 complications to doctors, right? 17 A. Yeah, it wasn't -- yes, I 18 didn't consider that a presentation. I 19 consider a presentation I get up at a podium 20 and I give a talk. It was mostly at 21 breakfast. Usually it's seven, eight people, 22 two, three show up and, "How do you do this, 23 how do you do that." 24 Q. But at none of these roundtable</p>	<p>1 Q. That's what I meant. I didn't 2 mean you get all 24 together at once. 3 Have you ever told the 4 residents they should never use TVT®? 5 A. Yes. 6 Q. Okay. Never use it? 7 A. No. 8 Q. And have you ever told them 9 they shouldn't use Gynemesh® PS? 10 A. Yes. 11 Q. When did you start doing that? 12 A. I can't tell you an exact time. 13 It's been years, but they see these patients 14 in the operating room with me, and they get a 15 sense of what they should do and shouldn't 16 do. 17 Q. There's a book chapter on here, 18 Chapter 18, Dekker, Inc., published in 2003. 19 Has that been updated since 20 that -- ever? 21 A. It's not been updated. 22 Q. Okay. So it doesn't sound like 23 you have; do you have anything in writing 24 about mesh used for SUI or prolapse?</p>

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<p>1 A. No.</p> <p>2 Q. Besides the residents, have you</p> <p>3 told any other doctors that they -- that in</p> <p>4 your opinion they should not use TVT® slings?</p> <p>5 A. Yes.</p> <p>6 Q. How many?</p> <p>7 A. The three or four that do</p> <p>8 slings at Mercy.</p> <p>9 Q. Okay.</p> <p>10 A. They ask me specifically what</p> <p>11 products they should use, and I give them my</p> <p>12 opinion.</p> <p>13 Q. Okay. Anybody else?</p> <p>14 A. Anyone who has asked me.</p> <p>15 Q. Well, do they ask you what</p> <p>16 products you prefer, or do you affirmatively</p> <p>17 tell them, "Whatever you do, don't use TVT®"?</p> <p>18 A. No, I think we have a</p> <p>19 discussion. They ask, you know, "How should</p> <p>20 I manage this, what product should I use,</p> <p>21 what approach should I use, how should I do</p> <p>22 it, which products are available." And I</p> <p>23 tell them what's available anymore out there</p> <p>24 is not many more manufacturers left, and I</p>	<p>1 A. It has the same issue with the</p> <p>2 round straw adaptation to the flat sling. I</p> <p>3 think it's pretty easy. We both learned in</p> <p>4 second grade that you can't put a square peg</p> <p>5 in a round hole. So all of these trocars</p> <p>6 create a round opening and then they put a</p> <p>7 square piece in there and it immediately</p> <p>8 causes it to roll. It's a design flaw in</p> <p>9 every manufacturer.</p> <p>10 So the only way to get around</p> <p>11 it is to have a sling that allows to you do</p> <p>12 surgery, open those spaces up, lay the sling</p> <p>13 nice and flat, and the only product out</p> <p>14 there, and it doesn't fray, is Desara.</p> <p>15 Q. Does the Advantage sling have a</p> <p>16 fraying issue?</p> <p>17 A. Yes.</p> <p>18 Q. All right. So you're critical</p> <p>19 of the Boston Scientific Advantage product</p> <p>20 both because it has an issue of fraying and</p> <p>21 because it has an improper instrumentation?</p> <p>22 A. Yes.</p> <p>23 Q. And does it also, in your view,</p> <p>24 recommend inappropriate technique?</p>
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<p>1 recently had this discussion when AMS pulled</p> <p>2 their product and BARD pulled their product.</p> <p>3 Some of the urology colleagues</p> <p>4 and gynecology colleagues asked what they</p> <p>5 should do and what my opinion was. I didn't</p> <p>6 overly twist their arm to use it or not to</p> <p>7 use it. I presented the pros and the cons of</p> <p>8 what I do, how I do it and why I do it and</p> <p>9 what's available out there, and I let them</p> <p>10 decide. Even though I feel strongly that</p> <p>11 TVT® is not a good product, I didn't, you</p> <p>12 know, ram it down their throat and say,</p> <p>13 "Don't use it."</p> <p>14 Q. What is on the market today for</p> <p>15 SUI mesh besides TVT® and Desara?</p> <p>16 A. Advantage Fit.</p> <p>17 Q. And that's a Boston Scientific</p> <p>18 product?</p> <p>19 A. Yes.</p> <p>20 Q. Do you believe that's a safe</p> <p>21 product?</p> <p>22 A. No, it's not as good as Desara.</p> <p>23 Q. Okay. And what's unsafe about</p> <p>24 it?</p>	<p>1 A. Yes.</p> <p>2 Q. So Advantage, Desara, TVT®, are</p> <p>3 there any other polypropylene sling products</p> <p>4 on the market that you're aware of?</p> <p>5 A. Coloplast.</p> <p>6 Q. Okay. And what's the name of</p> <p>7 theirs?</p> <p>8 A. The retropubic one is called</p> <p>9 Supris.</p> <p>10 Q. Have you used it?</p> <p>11 A. I have not.</p> <p>12 Q. Does it have an instrumentation</p> <p>13 problem?</p> <p>14 A. It has less of an</p> <p>15 instrumentation problem.</p> <p>16 Q. Okay. Do you believe it has an</p> <p>17 unsafe instrument with it?</p> <p>18 A. Not as much because the</p> <p>19 sling --</p> <p>20 Q. I didn't ask as much. I'm not</p> <p>21 there to ranking them yet. I'm just saying</p> <p>22 do you think it has a safe instrumentation or</p> <p>23 not?</p> <p>24 A. No, it does not.</p>

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<p>1 Q. It does not?</p> <p>2 A. It does not.</p> <p>3 Q. Okay. Does it have a safe</p> <p>4 recommended technique?</p> <p>5 A. It has a recommend technique.</p> <p>6 Q. Is the recommended technique</p> <p>7 safe?</p> <p>8 A. Not in my opinion.</p> <p>9 Q. Okay. And then the mesh</p> <p>10 itself, is the mesh itself safe?</p> <p>11 A. No.</p> <p>12 Q. Okay. So on the market today,</p> <p>13 is there anything else? That's the four.</p> <p>14 A. There's I-Stop. I don't see</p> <p>15 too much of that. Every now and then I get a</p> <p>16 patient that has a problem. I don't know</p> <p>17 who -- I don't know anyone that uses it</p> <p>18 around here. These patients come from far</p> <p>19 away.</p> <p>20 Q. So the four that are used with</p> <p>21 some regularity in the United States are</p> <p>22 the -- what did you say the Coloplast was</p> <p>23 called?</p> <p>24 A. Supris.</p>	<p>1 technique.</p> <p>2 Is the mesh itself safe with</p> <p>3 the Desara as far as you're concerned?</p> <p>4 A. The mesh has the same problem,</p> <p>5 it is polypropylene and degrades.</p> <p>6 Q. Do you consider it reasonably</p> <p>7 safe, the mesh itself?</p> <p>8 A. Same category as all the</p> <p>9 others.</p> <p>10 Q. So is it fair to say that all</p> <p>11 of the meshes that are on the market today,</p> <p>12 you consider all of them for SUI surgery to</p> <p>13 be unsafe?</p> <p>14 A. At this point in time with</p> <p>15 everything I've reviewed and everything I've</p> <p>16 learned, they are not safe.</p> <p>17 Q. Okay. None of them?</p> <p>18 A. None of them.</p> <p>19 Q. Okay. And then in ranking,</p> <p>20 okay, we'll doing ranking now.</p> <p>21 I assume because you use the</p> <p>22 Desara you believe it is the least unsafe?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. What's next? If it</p>
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<p>1 Q. The Supris, the Advantage, the</p> <p>2 TVT® and the Desara?</p> <p>3 A. Yes.</p> <p>4 Q. Okay. And all of those, as far</p> <p>5 as you're concerned, have unsafe</p> <p>6 instrumentation?</p> <p>7 A. Yes.</p> <p>8 Q. And all of them have an unsafe</p> <p>9 recommended technique?</p> <p>10 A. Yes.</p> <p>11 Q. And all of them, except the</p> <p>12 Desara, have an unsafe mesh?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. And maybe is the Desara</p> <p>15 a safe mesh or not?</p> <p>16 A. Yeah, I was thinking of the</p> <p>17 difference between the Supris and the pore</p> <p>18 size and the configuration and the diameter,</p> <p>19 comparing that to the TVT® and then comparing</p> <p>20 all of it to each other real quick.</p> <p>21 Q. So does Desara have a safe or</p> <p>22 unsafe mesh?</p> <p>23 I'm not talking about the</p> <p>24 instrumentation. I'm not talking about the</p>	<p>1 wasn't around, what would you use next?</p> <p>2 A. I probably wouldn't use any. I</p> <p>3 would probably go to cadaver or do something</p> <p>4 else.</p> <p>5 Q. So the other three, the</p> <p>6 Coloplast, the Boston Scientific and the</p> <p>7 TVT®, those SUI sling products, you just</p> <p>8 wouldn't use them, period, true?</p> <p>9 A. Definitely not.</p> <p>10 Q. True?</p> <p>11 A. Yes.</p> <p>12 Q. Are there any studies showing</p> <p>13 the long-term efficacy and complication of</p> <p>14 the Uretex or the Caldera Desara sling?</p> <p>15 A. No.</p> <p>16 Q. If the Uretex sling were still</p> <p>17 on the market, would you use it?</p> <p>18 A. Yes. That would be my</p> <p>19 preferred sling.</p> <p>20 Q. Above the Desara?</p> <p>21 A. Yes.</p> <p>22 Q. And what happened to it?</p> <p>23 A. It was a French company called</p> <p>24 Sofradim and something happened, it got sold,</p>

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<p style="text-align: right;">Page 146</p> <p>1 and I think Covidien purchased them. BARD</p> <p>2 didn't purchase them, so they lost the rights</p> <p>3 to import the sling.</p> <p>4 Q. So is that sling still on the</p> <p>5 market somewhere?</p> <p>6 A. I don't think so.</p> <p>7 Q. In your opinion about the</p> <p>8 relative merits of the various slings and</p> <p>9 instruments and techniques, you're not aware</p> <p>10 of any medical review or medical literature</p> <p>11 that makes a comparison like that and reaches</p> <p>12 those kinds of conclusions, true?</p> <p>13 A. True.</p> <p>14 Q. Okay. This is all essentially</p> <p>15 based on your personal opinion based on your</p> <p>16 personal experience?</p> <p>17 A. Yes.</p> <p>18 Q. Let's take 2005 to 2010.</p> <p>19 During that time period, were the IFU</p> <p>20 warnings any different for the Uretex or the</p> <p>21 Desara sling versus the TVT® in any material</p> <p>22 way?</p> <p>23 A. 2005?</p> <p>24 Q. To 2010, during that time</p>	<p style="text-align: right;">Page 148</p> <p>1 Uretex warnings and the TVT® warnings, were</p> <p>2 they different in any way that was</p> <p>3 significant to you during that time period?</p> <p>4 A. They were the same, but I want</p> <p>5 to qualify that I didn't read or look at the</p> <p>6 Caldera Desara until 2010. So I already knew</p> <p>7 what the IFU was for the Uretex and the TVT®.</p> <p>8 Q. But you looked -- when you</p> <p>9 looked at it in 2010, did you notice it being</p> <p>10 significantly different in terms of</p> <p>11 warnings --</p> <p>12 A. It had a lot -- the Desara had</p> <p>13 a lot more warnings.</p> <p>14 Q. Okay. In January 2010?</p> <p>15 A. Yes.</p> <p>16 Q. Do you know when it came on the</p> <p>17 market?</p> <p>18 A. Around that time.</p> <p>19 Q. Okay.</p> <p>20 A. I was looking for another</p> <p>21 sling, they were at a conference and I asked</p> <p>22 to be evaluated.</p> <p>23 Q. So the Uretex and TVT® slings</p> <p>24 had substantially the same warnings, right,</p>
<p style="text-align: right;">Page 147</p> <p>1 period?</p> <p>2 A. So I was not using Desara.</p> <p>3 Q. Well, I thought you said you</p> <p>4 started in 2010, that's why I included it.</p> <p>5 A. Okay. So from -- I started</p> <p>6 January 2010.</p> <p>7 Q. So starting January 2010 and</p> <p>8 going backward to 2003?</p> <p>9 A. Okay.</p> <p>10 Q. Which is when you started using</p> <p>11 the Uretex?</p> <p>12 A. Uh-huh.</p> <p>13 Q. During that time period, were</p> <p>14 the warnings in the IFU about the SUI slings</p> <p>15 any different in a material way between the</p> <p>16 Uretex IFU, the Desara IFU and the TVT® IFU?</p> <p>17 A. With respect to the material?</p> <p>18 Q. No, with respect -- by</p> <p>19 material, I meant relevant or a significant</p> <p>20 way. Let me reask the question. I'll get</p> <p>21 rid of the word "material."</p> <p>22 A. Okay.</p> <p>23 Q. From 2003 to 2010, the warnings</p> <p>24 in the IFU between the Desara warnings, the</p>	<p style="text-align: right;">Page 149</p> <p>1 during the time they were on the market in</p> <p>2 2003 to 2010?</p> <p>3 A. I think the Uretex had more</p> <p>4 warnings than the warnings that were in the</p> <p>5 TVT®.</p> <p>6 Q. Okay. During the 2003 to 2010</p> <p>7 time period?</p> <p>8 A. Yes.</p> <p>9 Q. And what was more about them?</p> <p>10 A. Injury to organs, talked about</p> <p>11 retention, talked about urgency. Just more</p> <p>12 of the routine things that you would expect</p> <p>13 from a sling.</p> <p>14 Q. There was more of that type of</p> <p>15 warning 2003 to 2010 with the Uretex product</p> <p>16 than the TVT®?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. And then the Desara was</p> <p>19 kind of a new generation sling as of January</p> <p>20 of 2010?</p> <p>21 A. Yes.</p> <p>22 Q. And it had more warnings?</p> <p>23 A. Yes.</p> <p>24 Q. And that was not surprising to</p>

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<p>1 you because there had been many more years of</p> <p>2 experience?</p> <p>3 A. Yes.</p> <p>4 Q. Now, in terms of warnings to</p> <p>5 doctors, manufacturers can get warning</p> <p>6 information to doctors through methods other</p> <p>7 than the IFU, true?</p> <p>8 A. Yes.</p> <p>9 Q. Professional education programs</p> <p>10 can provide warnings, right?</p> <p>11 A. Yes.</p> <p>12 Q. There can be surgeon monographs</p> <p>13 that can supply warnings?</p> <p>14 A. Yes.</p> <p>15 Q. Have you evaluated any of the</p> <p>16 sources of warnings that Ethicon gave to</p> <p>17 doctors other than the IFU?</p> <p>18 A. Yes, I've looked at some</p> <p>19 material.</p> <p>20 Q. In your report, do you make</p> <p>21 reference to any other materials that</p> <p>22 contained warnings other than the IFU?</p> <p>23 A. No. Because essentially</p> <p>24 information was the same as the IFU, and I</p>	<p>1 Ethicon to help educate doctors?</p> <p>2 Did you review those?</p> <p>3 A. I reviewed what was available</p> <p>4 to me.</p> <p>5 Q. Were there any different</p> <p>6 warnings in the professional education</p> <p>7 materials for the TVT® or the Gynemesh® PS</p> <p>8 more than in the IFU?</p> <p>9 A. No.</p> <p>10 Q. But you don't make -- with</p> <p>11 respect to your warning sections in both the</p> <p>12 Gynemesh® report and the TVT® report, the</p> <p>13 only warnings you refer to are warnings that</p> <p>14 are in the IFU, true?</p> <p>15 A. Yes. And I based that on the</p> <p>16 fact that that was a sure thing for me that</p> <p>17 that came with the kit.</p> <p>18 I don't know whether the</p> <p>19 surgeons viewed the video, looked at the</p> <p>20 pamphlets. I am not sure what they had done.</p> <p>21 But that was a constant.</p> <p>22 Q. But in any particular case, you</p> <p>23 would want to examine all of the information</p> <p>24 that was available from Ethicon to the</p>
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<p>1 relied on the sure bet that that information</p> <p>2 was always with the product rather than</p> <p>3 trying to second guess whether surgeon A, B</p> <p>4 or C did get this material.</p> <p>5 Q. Have you ever reviewed the</p> <p>6 surgeon monograph with respect to the</p> <p>7 Prolift® product, which was a Gynemesh® PS</p> <p>8 product?</p> <p>9 Have you evaluated that?</p> <p>10 A. What did you call it?</p> <p>11 Q. Surgeon monograph.</p> <p>12 A. Yes.</p> <p>13 Q. You've reviewed it?</p> <p>14 A. Yes.</p> <p>15 Q. Did that have the same or more</p> <p>16 or different warnings than the IFU?</p> <p>17 A. Had more pictures.</p> <p>18 Q. I didn't ask that.</p> <p>19 Did it have the same or</p> <p>20 different warnings than the IFU?</p> <p>21 A. Pretty much the same.</p> <p>22 Q. Okay. Did you review the</p> <p>23 professional education materials for the TVT®</p> <p>24 and the Gynemesh® PS that were used by</p>	<p>1 doctors in order to assess the adequacy of</p> <p>2 the warnings, true?</p> <p>3 A. Not if they're the same as the</p> <p>4 IFU. I think it's the same.</p> <p>5 Q. Your belief is that none of the</p> <p>6 materials had any different warnings in them?</p> <p>7 A. Correct.</p> <p>8 Q. Okay. Are there any warnings</p> <p>9 in an IFU for an SUI product that you thought</p> <p>10 were adequate?</p> <p>11 A. When I read it years ago, I</p> <p>12 thought it was adequate. Reading it today,</p> <p>13 none of them mention frequency. None of them</p> <p>14 mention how often these events occur, what</p> <p>15 the long-term consequences are.</p> <p>16 So they're all not adequate.</p> <p>17 Q. Okay. So when you read the</p> <p>18 TVT® IFU back in the early 2000s when you</p> <p>19 tried out the product, you thought the</p> <p>20 warnings were adequate at that time?</p> <p>21 A. I would have thought so, yes.</p> <p>22 Q. Okay. And you now have</p> <p>23 concluded that none of the IFUs for any of</p> <p>24 the mesh slings are adequate, true?</p>

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<p>1 A. With everything -- yes, with 2 everything I know today, they are not 3 adequate. 4 Q. None of them? 5 A. None of them. 6 Q. And you're saying this because 7 they don't state frequency? 8 A. Yes. 9 Q. Okay. Frequency of what? 10 A. How often is there a bladder 11 perforation, how often is there an exposure, 12 how much mesh contracture occurs, what are 13 the pore sizes, what happened to the 14 effective pore size. It's a very small 15 percentage of the information that any doc 16 needs to truly understand what he or she is 17 going to offer that patient and how to 18 counsel that patient. 19 So everything we tell a patient 20 before surgery is based on what our 21 understanding is and our best efforts at 22 explaining those risks and benefits to the 23 patients. So when it's very small, you don't 24 have enough information to truly counsel a</p>	<p>1 broad question first. 2 A. Yes. 3 Q. Do you have an opinion as to 4 the frequency of any of the potential 5 complications with a TVT®? 6 A. Two-part answer. 7 Q. Okay. 8 A. No, because I don't know the 9 denominator. 10 Q. Right. 11 A. And I don't know -- what I know 12 for certain are the patients that present to 13 me with those complications, and the patients 14 that present to other surrounding surgeons 15 with those complications. So the only way to 16 know that is to pool a very large number of 17 docs and figure out what it is. And even if 18 you found out what it was, you would have to 19 know the exact number of slings that went in. 20 Q. So do you believe that the 21 percentages of any of the complications with 22 the TVT® such as exposure, chronic foreign 23 body reaction, chronic pain with intercourse, 24 do you believe that is knowable?</p>
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<p>1 patient effectively. 2 Q. Today is your counseling of the 3 patient based more on the IFU or on your own 4 personal experience? 5 A. Both. 6 Q. Is it based more on one or the 7 other? 8 A. Probably more on my experience 9 at this point. 10 Q. Now, you say the IFU doesn't 11 tell frequency. 12 Do you have an opinion as to 13 what the frequency of exposure is with a 14 TVT®? 15 A. Yes. 16 Q. Because I thought -- here's the 17 reason I'm asking this. I thought we went 18 down this before, and I thought you said 19 rather than -- let me back up. 20 I thought you said before you 21 didn't have an opinion as to what the 22 percentage of frequency was with any of the 23 potential complications, and that's where I'm 24 getting confused. So I'm going to ask that</p>	<p>1 A. It can be knowable, yes. 2 Q. Okay. So do you know of anyone 3 or any paper or anything that would give 4 reliable percentages of the frequency of 5 complications such as dyspareunia, 6 contraction, exposure? 7 A. That study hasn't been done. 8 Q. Okay. And you're not aware of 9 any published papers on those topics? 10 A. Correct. 11 Even the Nilsson paper that's 12 cited on the back of the AUGS, SUFU, had 13 almost a -- half the patients went away. So 14 although they reported a few complications, 15 you don't know what the other 45, 47 patients 16 that got lost to follow-up were doing. 17 Q. So if a patient asked you, 18 "What is the percentage chance that I'm going 19 to have dyspareunia after a sling procedure," 20 you wouldn't be able to give them a 21 percentage? 22 A. The percentage I give -- I can 23 give them percentage on what I do. The way I 24 do.</p>

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<p>1 Q. I mean, the general, if they</p> <p>2 ask you just generally, not just you, Doc,</p> <p>3 just generally --</p> <p>4 A. 25 percent. 25 percent.</p> <p>5 Q. -- have dyspareunia?</p> <p>6 A. 25 percent can have</p> <p>7 dyspareunia.</p> <p>8 Q. Okay. What's your source for</p> <p>9 that number?</p> <p>10 A. That source is a paper by</p> <p>11 Hilary Cholhan.</p> <p>12 Q. And that's not -- is that</p> <p>13 long-term dyspareunia or temporary or both?</p> <p>14 A. It was de novo dyspareunia.</p> <p>15 Q. But long term or --</p> <p>16 A. It never got followed up,</p> <p>17 reported after that.</p> <p>18 Q. That's all products, not just</p> <p>19 TVT®?</p> <p>20 A. That was not just specific</p> <p>21 TVT®.</p> <p>22 Q. Is that what you tell patients</p> <p>23 then, that there's a 25 percent chance of</p> <p>24 dyspareunia with a general percentage with</p>	<p>1 A. True.</p> <p>2 Q. You said that you gave the</p> <p>3 general numbers like 85 percent cure and 7 or</p> <p>4 8 percent improvement with mesh slings.</p> <p>5 Remember that?</p> <p>6 A. That was with the TVT®.</p> <p>7 Q. TVT®.</p> <p>8 Are there any general numbers</p> <p>9 like that for other products?</p> <p>10 A. Yes.</p> <p>11 Q. What are they?</p> <p>12 A. I know the Mersilene sling by</p> <p>13 Steve Young had a 94 percent success rate.</p> <p>14 Q. Okay.</p> <p>15 A. Studies cite fascial slings</p> <p>16 95 percent.</p> <p>17 Q. I was talking about polyester</p> <p>18 slings.</p> <p>19 Are there any results on the</p> <p>20 Desara sling, the Uretex and the other ones</p> <p>21 that you've mentioned?</p> <p>22 MR. MATTHEWS: Object to the</p> <p>23 form. Those are not polyester slings.</p> <p>24 MR. BALL: Polypropylene. That</p>
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<p>1 mesh?</p> <p>2 A. No. Because I don't follow the</p> <p>3 manufacturer's instructions for placement.</p> <p>4 Q. What if they ask you what the</p> <p>5 general percentages of exposure or erosion,</p> <p>6 do you give a percentage?</p> <p>7 A. It's from 4 to 12. 4, 18,</p> <p>8 17 percent. It depends on --</p> <p>9 Q. I'm getting confused because a</p> <p>10 minute ago I asked you if there were any</p> <p>11 published studies about these percentages,</p> <p>12 and you said no, and now you're rattling off.</p> <p>13 I'm having trouble.</p> <p>14 A. There are some papers that talk</p> <p>15 about, but they're very small groups and the</p> <p>16 percentages are all over the board.</p> <p>17 Q. So I think I used the word</p> <p>18 "reliable," and I think that's -- so you're</p> <p>19 not aware of any reliable scientific papers</p> <p>20 that have been published that give what you</p> <p>21 think are reliable estimates of the</p> <p>22 percentage of complications of dyspareunia,</p> <p>23 pelvic pain, erosion, contraction, that type</p> <p>24 of thing, true?</p>	<p>1 was my error.</p> <p>2 MR. MATTHEWS: Okay.</p> <p>3 QUESTIONS BY MR. BALL:</p> <p>4 Q. Polypropylene slings, the other</p> <p>5 ones, is there any data that you find</p> <p>6 reliable about the success rates with other</p> <p>7 polypropylene slings?</p> <p>8 A. There's data to suggest that</p> <p>9 all slings have a high cure rate.</p> <p>10 Q. Of?</p> <p>11 A. 85, 90. Depending whether you</p> <p>12 look at objective or subjective data,</p> <p>13 sometimes that a little bit different.</p> <p>14 Q. So in terms of success rates,</p> <p>15 the TVT® sling is consistent with the other</p> <p>16 polypropylene slings that have been on the</p> <p>17 market the last 10 or 15 years, true?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. And in terms of</p> <p>20 complications, you don't have reliable data</p> <p>21 to compare the rate of complications with</p> <p>22 TVT® versus the other polypropylene slings</p> <p>23 that have been on the market the last 10 or</p> <p>24 15 years, true?</p>

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<p>1 A. True.</p> <p>2 Q. I wanted to ask you before we</p> <p>3 get into the Prolift® here, can you tell</p> <p>4 me --</p> <p>5 MR. BALL: Let's go off the</p> <p>6 record for a second.</p> <p>7 (Off the record at 11:52 a.m.)</p> <p>8 QUESTIONS BY MR. BALL:</p> <p>9 Q. Are you aware of any published</p> <p>10 scientific literature that is critical of the</p> <p>11 instruments used with TVT®?</p> <p>12 A. No.</p> <p>13 Q. Are you aware of any published</p> <p>14 scientific papers that are critical with the</p> <p>15 technique recommended in the IFU for the</p> <p>16 TVT®?</p> <p>17 A. No.</p> <p>18 Q. Are you aware of any scientific</p> <p>19 papers that are critical of the mesh design</p> <p>20 with the TVT®?</p> <p>21 A. No.</p> <p>22 Q. Okay. Have you read -- do you</p> <p>23 know which versions of the IFU -- well, let</p> <p>24 me back up.</p>	<p>1 instrument to do pelvic surgery, sacrospinous</p> <p>2 colpopexy.</p> <p>3 Q. Have those been commercialized,</p> <p>4 those products?</p> <p>5 A. Yes.</p> <p>6 Q. And did you write the warnings</p> <p>7 in the IFU?</p> <p>8 A. Yes.</p> <p>9 Q. Or just the technique?</p> <p>10 A. I wrote both.</p> <p>11 Q. Okay. Did anyone help you</p> <p>12 write the warnings?</p> <p>13 A. They gave me a handout on what</p> <p>14 it should include, and I wrote it.</p> <p>15 Q. If I wanted to have those IFUs,</p> <p>16 where would I get them?</p> <p>17 A. I don't know where you would</p> <p>18 get them at this time. Here's why: The</p> <p>19 company got sold. Currently the product got</p> <p>20 bought by -- let me think. I'll think of it</p> <p>21 in a second. I'll think of it.</p> <p>22 So I did not have a binding</p> <p>23 contract with the company that I did this for</p> <p>24 so when they sold it to -- oh, I'll think of</p>
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<p>1 Have you read the IFU that</p> <p>2 accompanies TVT® today?</p> <p>3 A. I don't think so.</p> <p>4 Q. Okay. So you don't have any</p> <p>5 opinion as to whether it's adequate or not,</p> <p>6 the warnings in there?</p> <p>7 A. No, I actually tried to click</p> <p>8 on it several times and it didn't download</p> <p>9 for me to get the latest version.</p> <p>10 Q. Other than being a doctor who</p> <p>11 reads warnings, do you have any other</p> <p>12 qualifications in the content of warnings?</p> <p>13 A. I'm not sure I understand the</p> <p>14 question.</p> <p>15 Q. What are your qualifications to</p> <p>16 judge the adequacy of warnings besides the</p> <p>17 fact that you're a doctor that reads IFUs?</p> <p>18 A. I've written several</p> <p>19 instructions for use on instruments I've</p> <p>20 designed.</p> <p>21 Q. For what?</p> <p>22 A. One was for a vaginal dilator</p> <p>23 for women that have a shortened vagina.</p> <p>24 Another one is for an</p>	<p>1 the name. Who are they?</p> <p>2 So I don't get any royalties or</p> <p>3 anything on that. I don't know where it's</p> <p>4 at.</p> <p>5 Q. Do you have copies of the IFUs</p> <p>6 for those products?</p> <p>7 A. I'm sure I don't.</p> <p>8 Q. Do you still use the products?</p> <p>9 A. I do not.</p> <p>10 Q. So you don't have any copies of</p> <p>11 IFUs that you've ever been involved in</p> <p>12 writing?</p> <p>13 A. That's correct.</p> <p>14 Q. In addition to the IFU,</p> <p>15 doctors -- in addition to the IFU and other</p> <p>16 materials the company might supply to doctors</p> <p>17 about warnings, the doctors also have a</p> <p>18 responsibility to keep up on continuing</p> <p>19 medical education about the procedures they</p> <p>20 perform, true?</p> <p>21 A. Sure, yes.</p> <p>22 Q. And they also have a</p> <p>23 responsibility to be aware, for example, of</p> <p>24 FDA notifications about the procedures they</p>

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<p>1 use, true?</p> <p>2 A. Yes.</p> <p>3 Q. And also the position</p> <p>4 statements and publications of the</p> <p>5 organizations they're members of, true?</p> <p>6 A. Yes.</p> <p>7 Q. And those can all be sources of</p> <p>8 information about warnings, true?</p> <p>9 A. Yes.</p> <p>10 Q. Are there more cites in your</p> <p>11 reports to company documents or peer-reviewed</p> <p>12 literature?</p> <p>13 A. Probably company documents.</p> <p>14 Q. Why is that?</p> <p>15 A. I thought that that was a very</p> <p>16 relevant source of things that were not in</p> <p>17 the peer-reviewed literature that truly spoke</p> <p>18 to the issues that the mesh had that were not</p> <p>19 evident by any peer-reviewed literature.</p> <p>20 Q. One reason I want to cover</p> <p>21 before we get into the Gynemesh® is I want to</p> <p>22 make sure that I understand and have on the</p> <p>23 record any communications that you recall</p> <p>24 having with anybody who worked for Ethicon.</p>	<p>1 where she was encouraging you to try TVT®,</p> <p>2 and you tried it, and you told her what your</p> <p>3 issues were, right?</p> <p>4 A. Yes.</p> <p>5 Q. Anything else about those</p> <p>6 communications that you can recall?</p> <p>7 A. No. Nice lady. She wanted me</p> <p>8 to try it, and I declined.</p> <p>9 Q. Well, you tried it and then</p> <p>10 declined using it more?</p> <p>11 A. Right. Yes.</p> <p>12 Q. By the way, did the two people</p> <p>13 you tried it on have any long-term problems,</p> <p>14 do you know?</p> <p>15 A. No, I don't think so.</p> <p>16 Q. And then you also mentioned a</p> <p>17 Will Irby at one point in time that you had a</p> <p>18 conversation with.</p> <p>19 A. Yes.</p> <p>20 Q. Who was he?</p> <p>21 A. I don't recall his exact title,</p> <p>22 but he had something to do with maybe the</p> <p>23 product manager for TVT®.</p> <p>24 Q. Okay. And what were the nature</p>
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<p>1 Okay?</p> <p>2 A. Okay.</p> <p>3 Q. All right. So, first of all, I</p> <p>4 think you said back in the early 2000s there</p> <p>5 was a person who encouraging you to try TVT®,</p> <p>6 right, and you gave us a name earlier in the</p> <p>7 deposition, and it escapes me?</p> <p>8 A. Hattie Loggie.</p> <p>9 Q. Okay. Other than her</p> <p>10 encouraging you to try TVT® in your SUI</p> <p>11 surgery and you telling her that you had some</p> <p>12 issues with it, anything else you remember</p> <p>13 about those communications?</p> <p>14 A. With her?</p> <p>15 Q. Yes.</p> <p>16 A. No, I remember there was -- I</p> <p>17 had communications with her.</p> <p>18 Q. I'm going to get to other</p> <p>19 people in a minute. I want to take them one</p> <p>20 at a time.</p> <p>21 A. I am sorry, ask that question</p> <p>22 again.</p> <p>23 Q. So you had communications back</p> <p>24 in the early 2000s with this woman about --</p>	<p>1 of your communications with him?</p> <p>2 A. He was introduced to me by</p> <p>3 Hattie Loggie as someone who might be a</p> <p>4 potential customer for using TVT®.</p> <p>5 Q. Okay. And what was the</p> <p>6 nature -- and then just tell me about those</p> <p>7 communications.</p> <p>8 A. My recollection is I met the</p> <p>9 man once. It was in my office. I asked</p> <p>10 about the product. He gave me a VCR at the</p> <p>11 time --</p> <p>12 Q. Was this before or after you</p> <p>13 tried it with --</p> <p>14 A. It was before.</p> <p>15 Q. Before?</p> <p>16 A. Yeah, it was before.</p> <p>17 Q. So this was kind of in</p> <p>18 conjunction with you trying it out the first</p> <p>19 time?</p> <p>20 A. Yeah. Yes.</p> <p>21 Q. Okay. Anybody else from</p> <p>22 Ethicon that you ever had any communications</p> <p>23 with about TVT®?</p> <p>24 A. Retropubic TVT®?</p>

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<p>1 Q. Yes.</p> <p>2 A. Now, there was a Jim Bly, but I</p> <p>3 think that was regarding TVT-Secur. So I</p> <p>4 think retropubic TVT® was Will Irby. There</p> <p>5 was Hattie Loggie. There was maybe her</p> <p>6 regional manager, Hattie's regional manager,</p> <p>7 that moved to Atlanta, but I can't recall his</p> <p>8 name.</p> <p>9 Q. And that was all about wanting</p> <p>10 you to try it out, and you tried it out, and</p> <p>11 you told them your thoughts?</p> <p>12 A. Yes.</p> <p>13 And after I tried it, I think</p> <p>14 Hattie set up this meeting. I remember</p> <p>15 they -- we went to dinner at Morton's and he</p> <p>16 asked me what my concerns were, and I relayed</p> <p>17 then my concerns about the tunneling, the</p> <p>18 curling, the rolling, the fraying, all of</p> <p>19 those things.</p> <p>20 Q. Now, did you get any specific</p> <p>21 training on using the TVT® before you tried</p> <p>22 it out?</p> <p>23 A. Yes.</p> <p>24 Q. What was the nature of that</p>	<p>1 Gynemesh®.</p> <p>2 A. Okay.</p> <p>3 Q. Prolapse products.</p> <p>4 A. Okay.</p> <p>5 MR. MATTHEWS: Well, he didn't</p> <p>6 give an opinion on Prolift®.</p> <p>7 MR. BALL: He gave an opinion</p> <p>8 about Gynemesh®.</p> <p>9 MR. MATTHEWS: Right. That's</p> <p>10 two different things.</p> <p>11 MR. BALL: Yeah, I understand.</p> <p>12 But his report is full of references</p> <p>13 to Prolift®. Okay.</p> <p>14 QUESTIONS BY MR. BALL:</p> <p>15 Q. Is Prolift® made out of</p> <p>16 Gynemesh® PS?</p> <p>17 A. It is.</p> <p>18 Q. All right. And did you ever</p> <p>19 have any communications with anybody from</p> <p>20 Ethicon connected with any product made out</p> <p>21 of Gynemesh® PS?</p> <p>22 A. So let me just think out loud</p> <p>23 for a second.</p> <p>24 Okay?</p>
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<p>1 training?</p> <p>2 A. I think there was some sort of</p> <p>3 course. I remember being flown. I don't</p> <p>4 remember where I flew, maybe it was</p> <p>5 Cincinnati. And there was a -- it was pretty</p> <p>6 impressive. There were a couple hundred</p> <p>7 people there. They took us in in buses, and</p> <p>8 they had live surgery, video and --</p> <p>9 Q. This is about TVT®?</p> <p>10 A. Yes.</p> <p>11 Q. And this was before you tried</p> <p>12 it the first time?</p> <p>13 A. Yes.</p> <p>14 Q. Did you ever go locally here</p> <p>15 and watch anybody or have any training from</p> <p>16 that?</p> <p>17 A. No.</p> <p>18 Q. Did you ever go over to France</p> <p>19 with Prolift®?</p> <p>20 A. No.</p> <p>21 Q. Or Gynemesh®?</p> <p>22 A. No.</p> <p>23 Q. Now, I've been talking about</p> <p>24 TVT®. Now I want to switch to Prolift® or</p>	<p>1 There was a young lady that</p> <p>2 drove me to Wichita, Kansas, to watch Dave</p> <p>3 Robinson, Dr. Robinson, who I had met a</p> <p>4 couple years prior, so I think worked for</p> <p>5 Ethicon. I recently just took out one of his</p> <p>6 posterior Prolift®s just a few days ago. So</p> <p>7 Dave Robinson. I don't recall the girl's</p> <p>8 name. Maybe Tracy. We went -- she drove me</p> <p>9 in her car, went to Wichita, Kansas, if I</p> <p>10 recall correctly, her, Dr. Robinson.</p> <p>11 Q. Dr. Robinson did the surgery?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. And you watched him do</p> <p>14 it?</p> <p>15 A. I watched him do it.</p> <p>16 Q. Okay. That's one episode.</p> <p>17 At that time had you used</p> <p>18 Gynemesh® PS any?</p> <p>19 A. I had not.</p> <p>20 Q. Okay. Any other communications</p> <p>21 you had with anybody from Ethicon about any</p> <p>22 Gynemesh® PS product?</p> <p>23 A. I'm thinking. I don't recall.</p> <p>24 If you have something to jog my memory.</p>

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<p>1 Q. What happened at the end of 2 that Wichita trip?</p> <p>3 A. Like typically what happens, 4 they want you to become a customer, try the 5 product. It seemed like Dr. Robinson put it 6 in pretty smooth. It seemed smooth. He 7 talked about what the advantages, 8 disadvantages were. I was very comfortable 9 doing vaginal surgery, doing sacrospinous. 10 And my interactions with Dave, a couple years 11 before he was interested in that instrument 12 that I developed for doing sacrospinous and 13 accessing that area of the pelvic floor and 14 that -- really don't think I have any other 15 recollection besides that.</p> <p>16 Anybody else? I think Jim Bly, 17 maybe Jim Bly brought me. I always like to 18 have stuff. I always like to play with it, 19 touch it, read things, look at the trocars. 20 I'm very hands-on, mechanical.</p> <p>21 Q. What's Jim Bly's role?</p> <p>22 A. He's a salesperson.</p> <p>23 Q. But you think that was about 24 the TVT-O or about the --</p>	<p>1 squared. It has --</p> <p>2 Q. So it's lighter?</p> <p>3 A. It's lighter, which is why TVT® 4 is considered heavy. And learning all of 5 this and thinking about it, reading about it 6 and everybody's in a lightweight mesh, you 7 think that someone would make a sling that's 8 lightweight. The pores have a funny 9 configuration. They're not the same. They 10 vary in size, and there's a fiber that runs 11 across it. So depending on how you measure 12 it, you can get something from very small to 13 1 millimeter to 1.5 to .3. It's all over.</p> <p>14 Q. Are the TVT® pore sizes that 15 consistent?</p> <p>16 A. Before you implant it, yes.</p> <p>17 Q. So far the differences between 18 TVT® and Gynemesh® PS is irregularity in pore 19 size and also the weight.</p> <p>20 Anything else?</p> <p>21 A. They're both polypropylene.</p> <p>22 Q. Is the polypropylene the same, 23 to your knowledge?</p> <p>24 A. Yes.</p>
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<p>1 A. No.</p> <p>2 Q. -- or the Secur?</p> <p>3 A. He was about Prolift® and 4 Secur.</p> <p>5 Q. Okay. And you think you did 6 have some interaction with him about a 7 Gynemesh® PS product Prolift®?</p> <p>8 A. It was about a posterior 9 Prolift®. I still have it.</p> <p>10 No. No, it was a total 11 Prolift®. It was a total.</p> <p>12 Q. And what was that communication 13 about?</p> <p>14 A. Basically wanting me to try it.</p> <p>15 Q. Okay. So any other 16 communications?</p> <p>17 A. Jogging my memory, that's all I 18 remember.</p> <p>19 Q. Okay. Do you know if there's 20 any difference between the mesh that is 21 Gynemesh® PS and the mesh used in TVT®?</p> <p>22 A. Yes, there is.</p> <p>23 Q. What's the difference?</p> <p>24 A. Well, PS is 45 grams per meter</p>	<p>1 Q. Okay.</p> <p>2 A. They're both polypropylene. 3 The TVT®'s used for slings. The Gynemesh® is 4 used for prolapse, cystocele, rectocele, 5 vaginal apex support. Variable size in the 6 pores. Color's different. It's got blue 7 stripes in the Gynemesh® where the early TVT® 8 was clear. Later TVT® is blue.</p> <p>9 Q. Is Gynemesh® PS a lightweight, 10 macroporous, monofilament mesh?</p> <p>11 A. It's medium weight, 12 macroporous, monofilament.</p> <p>13 Q. What's the dividing line 14 between light and medium --</p> <p>15 A. About 28, 28 -- I am sorry.</p> <p>16 Q. We've been doing great.</p> <p>17 A. Sorry.</p> <p>18 Q. Lightweight cutoff is what? 19 What were you just going to say?</p> <p>20 A. 28 to 30 grams per meter 21 squared.</p> <p>22 Q. And below, that's lightweight?</p> <p>23 A. Yes.</p> <p>24 Q. And 30 to what is medium</p>

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<p>1 weight?</p> <p>2 A. 60, 50.</p> <p>3 Q. And above 50 or 60 is</p> <p>4 heavyweight in your view?</p> <p>5 A. Yes.</p> <p>6 Q. I'm now going to be asking you</p> <p>7 principally about Gynemesh® PS, okay, so</p> <p>8 we're switching gears. It doesn't mean that</p> <p>9 there might not be some overlap, but we're</p> <p>10 switching gears.</p> <p>11 Doctor, can you tell me --</p> <p>12 first of all, have you ever used Gynemesh®</p> <p>13 PS?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. Kind of globally tell me</p> <p>16 what your experience is using that, and then</p> <p>17 I'll ask you more specific questions.</p> <p>18 A. I didn't like it.</p> <p>19 Q. Well, I didn't ask whether you</p> <p>20 liked it or not yet. I kind of figured you</p> <p>21 didn't like it or you wouldn't be here.</p> <p>22 What have you used Gynemesh® PS</p> <p>23 for?</p> <p>24 A. I've never used Gynemesh® PS.</p>	<p>1 Q. All right. Just remembered.</p> <p>2 When you do an implant of a TVT® -- or excuse</p> <p>3 me, an explant of a TVT®, the surgeries that</p> <p>4 come to you, what has been your success rate</p> <p>5 in resolving their problems?</p> <p>6 A. A percentage, you're looking</p> <p>7 for a percentage?</p> <p>8 Q. Yes.</p> <p>9 A. 95 percent.</p> <p>10 Q. Okay. And when you do that, do</p> <p>11 you do something else to deal with their</p> <p>12 stress urinary incontinence?</p> <p>13 A. Not at that time.</p> <p>14 Q. Okay. You take out the sling</p> <p>15 and kind of see how they do, is that the</p> <p>16 idea?</p> <p>17 A. Yes.</p> <p>18 Q. And sometimes you have to,</p> <p>19 what, put in another sling or do some other</p> <p>20 kind of procedure?</p> <p>21 A. Yes.</p> <p>22 Q. What percentage of the time</p> <p>23 that you've taken out a TVT® do you have to</p> <p>24 do some other kind of procedure?</p>
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<p>1 I've used Prolift®, which has Gynemesh® PS.</p> <p>2 Q. But I'm encompassing -- so</p> <p>3 what what have you used -- let me back up.</p> <p>4 Gynemesh® PS -- Prolift® is</p> <p>5 made out of Gynemesh® PS, right?</p> <p>6 A. Yes.</p> <p>7 Q. All right. The only Gynemesh®</p> <p>8 PS you've used is Prolift®?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. And how many times have</p> <p>11 you used Prolift®?</p> <p>12 A. Just once.</p> <p>13 Q. Okay. And when was that?</p> <p>14 A. Shortly after I visited Dave</p> <p>15 Robinson.</p> <p>16 Q. Okay. Did that patient have</p> <p>17 complications?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. In what nature?</p> <p>20 A. She had protracted pain.</p> <p>21 Q. Did it eventually go away?</p> <p>22 A. She didn't come back.</p> <p>23 Q. So you don't know?</p> <p>24 A. Don't know.</p>	<p>1 A. It's a great question. About</p> <p>2 half the time.</p> <p>3 Q. About half the time.</p> <p>4 And then the other half, you</p> <p>5 take it out and they're okay?</p> <p>6 A. They're fine. They're leaking</p> <p>7 a very small amount due to the scarring from</p> <p>8 all the surgery and with the experience they</p> <p>9 had, they would rather leak a little bit at</p> <p>10 that point rather than do anything else at</p> <p>11 all.</p> <p>12 Q. And when you do the other half</p> <p>13 of the time when you do a repeat surgery for</p> <p>14 SUI, what kind of surgery do you do?</p> <p>15 A. I offer them everything as I</p> <p>16 mentioned above. Because --</p> <p>17 Q. Just as if they're a new</p> <p>18 patient, so to speak?</p> <p>19 A. And they are sort of a new</p> <p>20 patient because I don't do partial removals.</p> <p>21 I do complete removals so the entire pelvis</p> <p>22 is sort of naïve except with scarring from</p> <p>23 multiple surgeries. But it gets her back to</p> <p>24 a starting point.</p>

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<p>1 Q. Okay. And you've been able --</p> <p>2 when you do these explant surgeries for TVT®,</p> <p>3 you've been able to remove all of the mesh?</p> <p>4 A. Yes.</p> <p>5 Q. All right. Now, so you tried</p> <p>6 Prolift® one time.</p> <p>7 Why did you not like it?</p> <p>8 A. I instantly saw the curling</p> <p>9 similar to what would happen with a TVT®</p> <p>10 because, again, the same concept.</p> <p>11 Q. The curling of the arms?</p> <p>12 A. The curling of the arms going</p> <p>13 through and the pulling and the fraying, and</p> <p>14 you can actually see the tissue get pulled --</p> <p>15 as you're pulling on the arm to tension it,</p> <p>16 you can actually see the rectal tissue</p> <p>17 pulling in with it. I regret not removing it</p> <p>18 right then and there.</p> <p>19 Q. On the one person?</p> <p>20 A. On that one person.</p> <p>21 Q. All right. So how many</p> <p>22 Gynemesh® PS products have you explanted?</p> <p>23 A. Does that include Prolift®?</p> <p>24 Q. Is that a Gynemesh® PS product?</p>	<p>1 explanted?</p> <p>2 A. So including everything with</p> <p>3 Prolift®?</p> <p>4 90.</p> <p>5 Q. And how many of those have been</p> <p>6 Prolift® versus surgeon-cut Gynemesh® PS?</p> <p>7 A. Surgeon-cut, 15.</p> <p>8 Q. Now, with respect to Gynemesh®</p> <p>9 PS, which is what your report is about here,</p> <p>10 okay, so that's about the mesh, right?</p> <p>11 A. Okay.</p> <p>12 Q. You're addressing the mesh</p> <p>13 that's cut by the surgeon and can be used for</p> <p>14 prolapse, true?</p> <p>15 A. Okay.</p> <p>16 Q. Right, that's what your report</p> <p>17 addresses?</p> <p>18 A. Yes.</p> <p>19 Q. Just so we're clear. Exhibit 3</p> <p>20 is a reported that's entitled "Gynemesh® PS,"</p> <p>21 and that is addressing the mesh that can be</p> <p>22 cut from a sheet and used to -- in various</p> <p>23 surgeries, correct?</p> <p>24 A. Yes. Just to be clear when we</p>
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<p>1 A. Okay. Yes.</p> <p>2 Q. Okay.</p> <p>3 A. In 2015?</p> <p>4 Q. No -- well, we'll start there.</p> <p>5 A. I know that number</p> <p>6 specifically.</p> <p>7 Q. Okay. Sure.</p> <p>8 A. About 30.</p> <p>9 Q. Okay. And were those all</p> <p>10 Prolift®?</p> <p>11 A. Yes.</p> <p>12 There's some Gynemesh® also.</p> <p>13 Piece Gynemesh®.</p> <p>14 Q. That was cut from a sheet?</p> <p>15 A. Yes.</p> <p>16 Q. All right. So how many of each</p> <p>17 of those?</p> <p>18 A. About seven Gynemesh® from a</p> <p>19 square piece, auto made.</p> <p>20 Q. In other words, a surgeon cuts</p> <p>21 it?</p> <p>22 A. Yes.</p> <p>23 Q. And through your career, how</p> <p>24 many Gynemesh® PS products have you</p>	<p>1 talk, are we adding Prolift®, or are we</p> <p>2 sticking to just the sheet? I'm a little</p> <p>3 confused.</p> <p>4 Q. If I have a Prolift® question,</p> <p>5 I'll ask you about it.</p> <p>6 A. Okay.</p> <p>7 Q. But I'm talking now about</p> <p>8 Gynemesh® PS, okay. The mesh itself, do you</p> <p>9 believe that that was so unsafe it never</p> <p>10 should have been sold?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. Why is that?</p> <p>13 A. It folds and curls because of</p> <p>14 its poor design. It bunches and rolls when</p> <p>15 it's placed. The vagina is not the anterior</p> <p>16 abdominal wall. And this mesh was designed</p> <p>17 for the anterior abdominal wall. And in the</p> <p>18 anterior abdominal wall the surgeon can lay</p> <p>19 it nice and flat. That's not the case in the</p> <p>20 vagina. The vagina is a tubular structure</p> <p>21 and the attachment points create oblique</p> <p>22 stress when you try to secure it. And then</p> <p>23 the vagina moves very differently. It has</p> <p>24 completely different tensile characteristic</p>

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<p>1 requirements than the anterior abdominal 2 wall. 3 It's really a product that 4 should have never been put in the vagina. 5 Q. Mesh in general? 6 A. Yes. 7 Q. All right. Not just Gynemesh®? 8 A. Mesh in general. 9 Q. So I want to make clear on 10 that. 11 It's your opinion that mesh in 12 general should not -- of any kind should be 13 used for treatment of prolapse, true? 14 A. Vaginally placed. 15 Q. Vaginally placed? 16 A. Because there is no mesh that's 17 designed specifically for the mechanical 18 requirements of the vagina. 19 Q. Okay. In your view, is 20 Gynemesh® PS the same as the mesh used for 21 hernia repair? 22 A. Yes. 23 Q. Okay. No differences? 24 A. No.</p>	<p>1 Q. Have you ever used it? 2 A. No. 3 Q. Okay. And you believe it's 4 unsafe, too? 5 A. Yes. 6 Q. And is that -- any others? 7 Any other products? 8 A. I was thinking. So there's 9 Gynemesh®, there's Boston Scientific, there's 10 Coloplast has Restorelle. Let me see who the 11 players are. So Boston Scientific Polyform, 12 Ethicon Gynemesh®, and Coloplast Restorelle. 13 I think that's it. 14 Q. Do you know surgeons today that 15 use polypropylene mesh for vaginally -- what 16 was the word you used? Vaginal entrance or 17 whatever? 18 A. What did I use, support? I'm 19 not sure what I used. 20 Q. For vaginal prolapse repair, 21 going through the vagina, not abdominally, do 22 you know surgeons today that use mesh for 23 that type of surgery? 24 A. So I want to answer the</p>
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<p>1 Q. So were there companies besides 2 Ethicon that made mesh for use with prolapse 3 repair? 4 A. Yes. 5 Q. Have you used any of their 6 products? 7 A. Have not. 8 Q. Okay. But you don't believe 9 any product ever made, any mesh product ever 10 made, for vaginal repair of prolapse is safe? 11 A. That is correct. 12 Q. Now, are there any mesh 13 products on the market today for vaginal 14 repair of prolapse? 15 A. Placed vaginally? 16 May I ask a question? Placed 17 vaginally? 18 Q. That's what I meant. 19 A. There are products that are 20 available at the surgeon's discretion to 21 place in the vagina. 22 Q. What are those? 23 A. There's a Boston Scientific 24 product Polyform.</p>	<p>1 question. I know there's people using it, 2 yes. 3 Q. Okay. 4 A. I don't know them personally, 5 but I know they're using it. 6 Q. So I want to make sure I 7 understand your opinion as to why Gynemesh® 8 is unsafe and should never have been sold. 9 One opinion I'm hearing is that 10 mesh in general is just not compatible with 11 use in the vagina, true? 12 A. Correct. 13 Q. Okay. Any other specific 14 criticisms you have of Gynemesh® PS from a 15 design standpoint? 16 A. It's heavier, stronger than it 17 needs to be placed in the vagina. Even 18 though it is sort of medium weight, 19 macroporous, monofilament with pore sizes 20 that in certain areas are above a millimeter, 21 in other areas they're not, which enhances 22 bridging fibrosis and scarring. The vagina 23 is just not an organ -- the vagina doesn't 24 have an organ that's conducive for placing</p>

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<p>1 mesh. Let's see if I wrote anything else.</p> <p>2 And obviously all the things we</p> <p>3 mentioned about polypropylene and the chronic</p> <p>4 inflammation and the scarring, especially in</p> <p>5 a vagina, because the vagina shrinks</p> <p>6 differently than the anterior abdominal wall.</p> <p>7 The anterior abdominal wall shrinks in the</p> <p>8 plane of which the mesh is placed.</p> <p>9 Q. You mean when you're doing a</p> <p>10 sling?</p> <p>11 A. Well, when you're -- let me</p> <p>12 back up.</p> <p>13 Q. Okay.</p> <p>14 A. I meant the abdominal wall,</p> <p>15 when Gynemesh® is placed in the abdominal</p> <p>16 wall. It's in a sheet.</p> <p>17 Q. Okay.</p> <p>18 A. But when it's placed in the</p> <p>19 vagina, it's curvilinear. So just like scar</p> <p>20 will shrink a little bit, it will shrink in a</p> <p>21 way that will make the vagina not functional.</p> <p>22 Q. Does the mesh actually shrink,</p> <p>23 or is the contraction connected with the</p> <p>24 formation of scar tissue?</p>	<p>1 long-term, tape-induced adverse effects.</p> <p>2 You're aware of that</p> <p>3 conclusion, right?</p> <p>4 A. Yes.</p> <p>5 Q. All right. And you did not</p> <p>6 cite that paper in your report concerning</p> <p>7 TVT®, correct?</p> <p>8 A. Yes.</p> <p>9 Q. All right. And why did you not</p> <p>10 cite that paper?</p> <p>11 A. The paper started with 90</p> <p>12 patients, ended up with 45.</p> <p>13 Q. Followed over 17 years?</p> <p>14 A. But it's half the population.</p> <p>15 So what if the other half had a problem.</p> <p>16 Actually I did some calculations and some of</p> <p>17 the percentages that he mentions in there are</p> <p>18 not accurate. He's using -- he's not</p> <p>19 using -- the 90, he's using less than 90, and</p> <p>20 it ends up being a higher percentage than</p> <p>21 what it should be.</p> <p>22 So I had some issues about the</p> <p>23 paper, and the calculations were off. Half</p> <p>24 the patients were gone. It wasn't -- the</p>
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<p>1 A. The whole unit shrinks. It's a</p> <p>2 combination of the bridging fibrosis, even</p> <p>3 scar without mesh is going to shrink. But if</p> <p>4 you add chronic inflammation to it and you</p> <p>5 add an attachment point and it pulls</p> <p>6 together, it's going to shrink. It's not</p> <p>7 that the -- it's not that the fiber in the</p> <p>8 mesh shrinks. It's not like the</p> <p>9 polypropylene itself is going to shrink. But</p> <p>10 the gaps between the polypropylene shrink.</p> <p>11 Q. That's part of the scarring</p> <p>12 process?</p> <p>13 A. And the bridging fibrosis from</p> <p>14 chronic inflammation.</p> <p>15 MR. MATTHEWS: When you get to</p> <p>16 a break point.</p> <p>17 MR. BALL: Sure, we can do that</p> <p>18 right now.</p> <p>19 (Off the record at 12:22 p.m.)</p> <p>20 QUESTIONS BY MR. BALL:</p> <p>21 Q. Doctor, the Nilsson paper from</p> <p>22 2013 that we referred to earlier concluded</p> <p>23 the TVT® operation is durable for 17 years</p> <p>24 with a high satisfaction rate and no serious</p>	<p>1 paper would be much more meaningful if</p> <p>2 95 percent of the patients were there</p> <p>3 followed up.</p> <p>4 Q. But you don't have any papers</p> <p>5 cited in your report about TVT® that reached</p> <p>6 a contrary conclusion that TVT® had a low</p> <p>7 satisfaction rate with serious long-term,</p> <p>8 taper-induced adverse effects?</p> <p>9 Do you have any of that -- any</p> <p>10 papers to that effect cited in your report,</p> <p>11 true?</p> <p>12 A. Would you repeat that last</p> <p>13 sentence?</p> <p>14 Q. You don't have any papers cited</p> <p>15 in your report that says TVT® does not have a</p> <p>16 satisfaction rate and has serious long-term,</p> <p>17 adverse effects?</p> <p>18 A. No.</p> <p>19 Q. True?</p> <p>20 A. True.</p> <p>21 Q. Do you have in your report</p> <p>22 cited the Svenningsen from 2013 that</p> <p>23 concludes long-term objective and subjective</p> <p>24 outcome after retropubic TVT® is excellent</p>

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<p>1 with a low number of reoperations, even in a 2 nonselected cohort of patients? 3 Do you have that paper? 4 A. I would have to look. 5 Can I see the paper? 6 Q. Just asking if you have it 7 cited in your report. 8 A. No, I don't. 9 Q. Okay. Why not? 10 A. I tried to cite every paper 11 that I could get my hands on, look at 12 everything that was available to me. There's 13 thousands and thousands of papers on TVT® and 14 slings and et cetera. 15 Q. You don't cite a single paper 16 in your report that gives favorable findings 17 with respect to TVT®, true? 18 A. No, I do. I mentioned the 19 Thomas trial, and it says that in the short 20 term, these patients have good outcomes. 21 Now, how many papers do you 22 really need to cite in there that in the 23 short term the sling works? 24 Q. Yeah, let me ask you this: You</p>	<p>1 option for the treatment of female SUI 2 recording a very high cure rate with low 3 complications after a ten-year follow-up? 4 You're not aware of that 5 conclusion? 6 A. Many times -- 7 Q. Are you aware of that 8 conclusion? 9 A. No. 10 Many times TVT® doesn't really 11 mean Ethicon TVT®; it's a generic term that 12 talks about slings in general. 13 Q. Well, this one says it was 14 Ethicon. 15 A. Okay. 16 Q. But you're not familiar with 17 the study? 18 A. No. 19 Q. And you did not cite it in your 20 report? 21 A. Correct. 22 Q. And, in fact, did you make a 23 specific search to see if you could find 24 studies about the long-term efficacy and</p>
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<p>1 don't have any papers that give favorable 2 outcomes for long-term studies on TVT®, true? 3 A. There's not a good, long-term 4 study to cite. 5 Q. Well, this one says long 6 term -- this Svenningsen paper is termed 7 long-term follow-up of the retropubic TVT® 8 procedure, and you did not -- were not 9 familiar with it and did not cite it, true? 10 A. Can I see it again? 11 Q. Well, I'm just asking you if 12 you cited it in your paper, in your report. 13 A. I didn't cite it. 14 Q. And then there's another paper 15 by Serati, et al., "Tension-Free Vaginal Tape 16 for the Treatment of Urodynamic Stress 17 Incontinence: Efficacy and Adverse Effects 18 at a Ten-Year Follow-Up." 19 Did you cite that paper in your 20 report? 21 A. I don't think so. 22 Q. Okay. And it concludes the 23 ten-year results of this study seem to 24 demonstrate that TVT® is a highly effective</p>	<p>1 concerns related to TVT®, did you make that 2 search in connection with your report? 3 A. Yes, I did. 4 Q. And you found the Nilsson paper 5 or were familiar with the Nilsson paper? 6 A. Yes. 7 Q. And decided not to mention it 8 in your report? 9 A. Yes. 10 Q. And you did not find the Serati 11 or the Svenningsen paper? 12 A. Correct. 13 MR. MATTHEWS: Do you have an 14 extra copy of those that I can look 15 at? If you don't mind. 16 MR. BALL: I don't mind. 17 QUESTIONS BY MR. BALL: 18 Q. With respect to Gynemesh® PS, 19 did you make a search for any papers 20 regarding multi-year follow-up with respect 21 to use of Gynemesh® PS products in women for 22 prolapse? 23 A. Yes. 24 Q. Okay. Do you have the</p>

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<p>1 Jacquetin 2013 paper cited in your Gynemesh® 2 report? 3 A. Let me take a look. 4 Doesn't look like that I do. 5 Q. Do you have the -- so you're 6 not aware of the conclusion from that report, 7 in that study? 8 A. No. 9 Q. Do you have cited in your paper 10 the Landesherr 2012 publication paper, study, 11 surgical intervention after transvaginal 12 Prolift® mesh repair, retrospective 13 single-center study including 524 patients 14 with three years median follow-up. 15 Did you have that study cited 16 in your -- 17 A. I excluded studies that had 18 Prolift® because I was not writing a report 19 on Prolift®. 20 Q. Well, isn't Prolift® made from 21 Gynemesh® PS? 22 A. There's a world of difference 23 between Prolift® and Gynemesh® PS. 24 Q. Excuse me, is Prolift® made</p>	<p>1 A. Yes. 2 Q. Okay. You cited those. You 3 gave percentages and everything in your 4 report, right? 5 A. I -- 6 Q. Excuse me, didn't you do that? 7 A. Yes. 8 Q. But you did not cite a single 9 piece of published literature relating to 10 Prolift®, true? 11 A. Correct. 12 Q. And do you think that's 13 scientifically appropriate to cherry-pick on 14 what Prolift® documents and literature you 15 use? 16 Is that scientifically 17 appropriate? 18 MR. MATTHEWS: Objection to the 19 form. 20 QUESTIONS BY MR. BALL: 21 Q. I'll withdraw the question and 22 ask it this way. 23 Do you think it's 24 scientifically appropriate to include in your</p>
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<p>1 from Gynemesh® PS? 2 A. Yes. 3 Q. Do you cite multiple internal 4 company documents referring to Prolift®? 5 A. Yes. 6 Q. And yet you don't cite any 7 independent literature relating to Prolift®, 8 true? 9 A. That's correct. Because -- 10 MR. MATTHEWS: Well, let me 11 finish his answer. 12 THE WITNESS: Because there's a 13 world of difference between adding 14 arms that extend into the levators and 15 the forces exerted that are on that 16 mesh as opposed to a small piece that 17 doesn't have arms exerted. 18 QUESTIONS BY MR. BALL: 19 Q. So why did you cite numerous 20 internal documents and testimony 21 concerning -- in fact, you cited studies, the 22 clinical study reports. 23 Those were Prolift® devices, 24 weren't they?</p>	<p>1 report numerous references to Prolift® from 2 internal documents and clinical study reports 3 and not refer to any Prolift® literature? 4 A. Yes. 5 Q. Okay. 6 A. And the reason for that is I 7 was looking at the material, not the way the 8 material works in the body with arms. 9 You cannot take a small piece 10 of mesh and place it between the vagina and 11 the bladder without arms and have that same 12 clinical consequence with arms. 13 Q. Well, then why did you put all 14 of the Prolift® study results and all the 15 Prolift® references to internal documents, 16 why did you put those in your report? 17 See, I understand that 18 Gynemesh® PS cut from a sheet, you believe, 19 is different than Prolift®. I understand 20 that. 21 But how come you put in some 22 Prolift® documents and didn't put in any 23 Prolift® literature? That's what I don't 24 understand.</p>

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<p>1 A. Because there's a difference</p> <p>2 between the clinical execution of putting in</p> <p>3 Prolift® with arms that extend into the</p> <p>4 levators as opposed to putting in a small</p> <p>5 piece of Gynemesh®.</p> <p>6 Q. Didn't you refer extensively to</p> <p>7 results where Prolift® with arms were put in?</p> <p>8 Look at page 21.</p> <p>9 A. Yes.</p> <p>10 Q. You have extensive discussion</p> <p>11 of Prolift® -- of a Gynemesh® PS product with</p> <p>12 arms, the Prolift® product, put in. You have</p> <p>13 extensive discussion of that at page 21,</p> <p>14 don't you, sir?</p> <p>15 A. Yes.</p> <p>16 Q. And it goes on over, you have a</p> <p>17 more extensive discussion at page 22,</p> <p>18 correct?</p> <p>19 My only point, Doctor, is that</p> <p>20 pages 21 and 22, at least, you have extensive</p> <p>21 discussions of studies done installing</p> <p>22 Prolift® in women, implanting Prolift® in</p> <p>23 women, true?</p> <p>24 A. And I used those from the point</p>	<p>1 A. I believe so.</p> <p>2 Q. Okay. Did you make in your --</p> <p>3 in your evaluation in this case, did you</p> <p>4 consider to some degree internal documents</p> <p>5 and internal data related to Prolift® devices</p> <p>6 made out of Gynemesh® PS?</p> <p>7 A. I considered everything that</p> <p>8 was available.</p> <p>9 Q. Including that?</p> <p>10 A. Yes.</p> <p>11 Q. Did you make any search for</p> <p>12 literature about these long-term success</p> <p>13 rates of Gynemesh® PS when used in Prolift®</p> <p>14 devices?</p> <p>15 Did you make that search?</p> <p>16 A. Yes.</p> <p>17 Q. And did you find these three</p> <p>18 papers that I have -- in your search these</p> <p>19 three papers that I mentioned?</p> <p>20 A. I did not find those.</p> <p>21 Q. Now, in the --</p> <p>22 MR. MATTHEWS: Well, I am</p> <p>23 sorry. Three papers that you</p> <p>24 mentioned?</p>
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<p>1 of view of shrinkage of the material.</p> <p>2 Q. Those paragraphs don't say,</p> <p>3 "The only reason I'm citing this is about</p> <p>4 shrinkage." You start off saying, "An</p> <p>5 Ethicon clinical study for pelvic prolapse</p> <p>6 repair involving the Prolift® showed</p> <p>7 serious" --</p> <p>8 A. A transvaginal Gynemesh® for</p> <p>9 pelvic organ prolapse repair demonstrated to</p> <p>10 Ethicon that the mesh was not effective</p> <p>11 prolapse treatment according to Ethicon's own</p> <p>12 criteria.</p> <p>13 Q. "This study, which performed by</p> <p>14 physicians who helped develop the Prolift®</p> <p>15 device," right?</p> <p>16 A. Yes.</p> <p>17 Q. And it's all about the</p> <p>18 Prolift®, isn't it?</p> <p>19 A. No, it says that they helped</p> <p>20 develop the Prolift® device.</p> <p>21 Q. Is this data placed upon a</p> <p>22 Gynemesh® used in a Prolift® device with</p> <p>23 arms, the data at pages 21 and 22 of your</p> <p>24 report?</p>	<p>1 MR. BALL: Jacquetin,</p> <p>2 Landesherr --</p> <p>3 MR. MATTHEWS: Okay.</p> <p>4 MR. BALL: I didn't quite get</p> <p>5 to the third one. The Altman paper is</p> <p>6 also not mentioned there.</p> <p>7 QUESTIONS BY MR. BALL:</p> <p>8 Q. The one-year follow-up, you</p> <p>9 didn't mention that one in your report, did</p> <p>10 you, sir?</p> <p>11 A. No.</p> <p>12 MR. BALL: Your point is well</p> <p>13 taken. I had forgotten the Altman</p> <p>14 paper.</p> <p>15 QUESTIONS BY MR. BALL:</p> <p>16 Q. Now, Doctor, when you removed</p> <p>17 Gynemesh® PS, whether Prolift® or</p> <p>18 non-Prolift®, when you removed Gynemesh® PS</p> <p>19 in these explant surgeries you do, what is</p> <p>20 your success rate there?</p> <p>21 A. How are we defining success</p> <p>22 rate?</p> <p>23 Q. Well, how would you define it?</p> <p>24 A. Well, there's two aspects: One</p>

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<p>1 is how much do you remove, and two, how are</p> <p>2 the patients doing.</p> <p>3 Q. Okay. So give me the results</p> <p>4 under both of them.</p> <p>5 A. If it's a Prolift® that hasn't</p> <p>6 been revised or manipulated in the office, I</p> <p>7 can usually get out the vast -- all of the</p> <p>8 mesh between the rectum and the vagina.</p> <p>9 The arms, depending how they're</p> <p>10 placed, because there's variable there. For</p> <p>11 example, in the one I just took out a few</p> <p>12 days ago from my friend Dave Robinson, I</p> <p>13 removed the woman's entire right arm out of</p> <p>14 the gluteus muscles. On her left side, I</p> <p>15 removed half the arm. Almost invariably</p> <p>16 these patients are pain free after surgery.</p> <p>17 Not 100 percent. And you can't get</p> <p>18 100 percent of the mesh out.</p> <p>19 You can get more of the</p> <p>20 Prolift® out posteriorly. The anterior</p> <p>21 Prolift® you can, again, remove most of the</p> <p>22 mesh from between the vagina and the bladder.</p> <p>23 The arms that go around the descending pubic</p> <p>24 ramus, they're very hard to get. About</p>	<p>1 quality of life. They don't have the quality</p> <p>2 of life that they had before because they've</p> <p>3 been through whatever they've been through.</p> <p>4 So the way I can answer the</p> <p>5 question is improved quality of life with</p> <p>6 pain reduction, about 80 percent of the</p> <p>7 patients have no pain. The other 20 percent</p> <p>8 have some degree of pain.</p> <p>9 They still have their prolapse.</p> <p>10 Their prolapse comes back. For the</p> <p>11 posterior.</p> <p>12 For the anterior, it's a little</p> <p>13 bit less because there's more arms.</p> <p>14 Q. A little bit less what?</p> <p>15 A. Improvement. 70 to 75 percent.</p> <p>16 Q. Have pain go away?</p> <p>17 A. The pain goes away.</p> <p>18 The other 25 percent still have</p> <p>19 some pain. 7 percent of the women have a</p> <p>20 scarred, narrowed, foreshortened vagina, and</p> <p>21 there's all kinds of variations of residual</p> <p>22 prolapse that occurs.</p> <p>23 Q. When you do the explant</p> <p>24 procedure, do you have to deal with the</p>
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<p>1 50 percent of the time you can remove the</p> <p>2 distal arm and about 20 percent of the time</p> <p>3 you can remove the entire apical arm.</p> <p>4 If it's a total Prolift® and</p> <p>5 that bridge of mesh between the anterior and</p> <p>6 posterior have combined together, it is a</p> <p>7 big, wadded, folded, scarred, difficult</p> <p>8 nightmare.</p> <p>9 Q. So let's take the women having</p> <p>10 success from a quality of life and pain</p> <p>11 standpoint.</p> <p>12 What is your percentage of</p> <p>13 success with explant surgery on Gynemesh®</p> <p>14 products?</p> <p>15 A. Could you ask the question</p> <p>16 again differently?</p> <p>17 Q. Yeah.</p> <p>18 With respect to women from</p> <p>19 becoming an improvement in quality of life</p> <p>20 and not having ongoing problems using --</p> <p>21 defining that as success, what is your</p> <p>22 success rate with explanting Gynemesh®</p> <p>23 products?</p> <p>24 A. So they have an improved</p>	<p>1 recurrent prolapse?</p> <p>2 A. Not at that moment. You can't.</p> <p>3 The dissection is extensive to remove it.</p> <p>4 Q. On most of the patients you</p> <p>5 see, do they need a follow-up surgery for</p> <p>6 recurrent prolapse?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. Is that usually</p> <p>9 performed by you or someone else?</p> <p>10 A. If they return, I'll do it.</p> <p>11 But they don't all come back.</p> <p>12 Q. The great majority of the</p> <p>13 patients need -- after the mesh is removed,</p> <p>14 still need treatment for prolapse, surgical</p> <p>15 treatment?</p> <p>16 A. Some. I don't have an exact</p> <p>17 number. These patients live many states</p> <p>18 away, and they're seeking my services for</p> <p>19 removing the mesh and then they may go</p> <p>20 somewhere else.</p> <p>21 Q. But your estimate would be the</p> <p>22 great majority of them will need treatment</p> <p>23 for recurrent prolapse?</p> <p>24 A. The great majority of them have</p>

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<p>1 prolapse. I don't know if they'll seek 2 treatment. 3 Q. Prolapse of grade 2 or greater? 4 A. One segment, two segments, 5 some, yes. 6 Q. So let's get away from the 7 explant now and just talk to women that come 8 to you needing surgical treatment for 9 prolapse. 10 All right. What alternatives 11 do you offer them? 12 A. Well, if they need an A and P 13 repair, cystocele, rectocele, I just use 14 native tissue. 15 If they need an apical 16 procedure, I will use polypropylene or 17 suture. 18 Q. So if they need a posterior, 19 anterior repair, you'll use what? 20 A. Just native tissue. Absorbable 21 sutures. 22 Q. And if they need an apical 23 repair, is that an abdominal procedure? 24 A. Yes.</p>	<p>1 A. I think that's a good question. 2 Q. You've only said that twice 3 today. I hope I have asked more than two 4 good questions. 5 A. So the vast majority of 6 surgeons will do a sacrocolpopexy and tunnel 7 between the vagina and the rectum 8 abdominally. That's still placing the mesh 9 vaginally. They may think there's an 10 advantage because there's no incision. 11 That's not been my experience. Those women 12 still have problems because of placing that 13 mesh that way. 14 So what I do is I limit the 15 mesh to the apex. So the lancing had three 16 levels: Apex, middle vagina, and distal 17 vagina. So a TVT® is on the distal anterior 18 segment, and the sacrocolpopexy is on the 19 apex. I only place 2 centimeters on each 20 side of the Y. So in total, I place 21 4 centimeters of mesh by 3 centimeters. So a 22 very, very small piece. 23 Q. So it's two pieces that are 2 24 centimeters by 3 centimeters?</p>
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<p>1 Q. And you'll use mesh with that? 2 A. Yes. 3 Q. And what kind of mesh? 4 A. I use BARD Alyte. 5 Q. How does that differ from 6 Gynemesh® PS? 7 A. The grams per meter squared of 8 Gynemesh® is 45. The grams per meter squared 9 for the vaginal arms of the Alyte is 17. So 10 it's very light. And that's less -- that's 11 about a third of the weight. The pores are 12 much larger. The filaments are much smaller, 13 and even there, I still sew the graft apart 14 to increase the pore size. 15 Q. And what is the size of the 16 mesh, once you -- is this cut from a sheet, 17 the stuff you use for the ASC? 18 A. Yes. 19 Q. This is for an abdominal -- 20 A. Yes. 21 Q. -- sacrocolpopexy, right? 22 A. Yes. 23 Q. And what is the size that you 24 cut it from the sheet?</p>	<p>1 A. No. 2 Q. Okay. I'm sorry. 3 A. It's a Y and at the crux of the 4 Y is 2 centimeters. So if you laid it open, 5 it's 4 centimeters by at the middle part 6 3 centimeters, and it's actually a circle. 7 Q. So it's a circle of mesh? 8 I'm just trying to get the 9 piece of mesh that you cut out before you put 10 it in, how big that? 11 A. It's very, very small. 12 Q. How big? 13 A. It's a circle that has a 14 diameter of 3 centimeters. 15 Q. Okay. All right. So not all 16 ASCs are done abdominally, is that what I 17 just heard you say? 18 A. No, all ASCs are done 19 abdominally. They don't all use mesh. 20 Q. Okay. You're talking about not 21 all apical repairs are done abdominally? 22 A. Yes. 23 Q. Okay. What is the recognized 24 in the medical community success rate for</p>

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<p>1 native tissue repairs for anterior prolapse?</p> <p>2 A. Would you ask the question</p> <p>3 again?</p> <p>4 Q. Yeah.</p> <p>5 What in the medical community</p> <p>6 in your opinion is recognized as the success</p> <p>7 rate for anterior prolapse when you use</p> <p>8 native tissue repairs?</p> <p>9 A. What's quoted is 70 percent</p> <p>10 success.</p> <p>11 Q. Okay. What do you tell</p> <p>12 patients?</p> <p>13 A. I tell them the reason there's</p> <p>14 only 70 percent success is they have other</p> <p>15 defects that didn't get fixed. So the</p> <p>16 patient returns with prolapse because rarely</p> <p>17 do you have -- and there is a paper out there</p> <p>18 that says there's no such thing as a</p> <p>19 cystocele, that all cystoceles have an apical</p> <p>20 component. So if you're only fixing the</p> <p>21 cystocele, you're going to get an apical</p> <p>22 component.</p> <p>23 Now, the Altman paper does say</p> <p>24 that if you put mesh anteriorly on a</p>	<p>1 really is skewed because there's not a single</p> <p>2 paper in the literature, not one, that looks</p> <p>3 at outcomes of native tissue that addresses</p> <p>4 the anterior, the apex, the enterocele, the</p> <p>5 rectocele, and the perineum. Not a single</p> <p>6 paper.</p> <p>7 Q. So if someone repairs an</p> <p>8 anterior prolapse and repairs the apical at</p> <p>9 the same time, do you have an opinion as to</p> <p>10 what the success rate is?</p> <p>11 A. Of the anterior and the apical,</p> <p>12 yes. If it's a good repair and it holds, it</p> <p>13 shouldn't come back.</p> <p>14 Q. No, what is the recurrence</p> <p>15 rate, I should say?</p> <p>16 A. I'm not sure I understand the</p> <p>17 question.</p> <p>18 Q. In the medical community if you</p> <p>19 do an anterior prolapse repair and at the</p> <p>20 same time do a repair apically with native</p> <p>21 tissue, is there a recognized recurrence rate</p> <p>22 for that?</p> <p>23 A. Yes.</p> <p>24 Q. What is that?</p>
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<p>1 cystocele, it does better if you do native</p> <p>2 tissue. However, how many of those patients</p> <p>3 really would have done well with a native</p> <p>4 tissue repair with an apical component. The</p> <p>5 reason --</p> <p>6 Q. You mean a native tissue apical</p> <p>7 component as well as the anterior?</p> <p>8 A. Yes.</p> <p>9 Q. Okay.</p> <p>10 A. So that is well-documented that</p> <p>11 there are patients that have a cystocele, but</p> <p>12 really it's a displacement cystocele, and</p> <p>13 it's displaced because the top of the vagina</p> <p>14 is coming down as opposed to a distension.</p> <p>15 So on a distension, sure, you</p> <p>16 could do a native tissue repair and you're</p> <p>17 going to get a much higher success rate than</p> <p>18 if you have a displacement cystocele. If you</p> <p>19 have a displacement cystocele, if you don't</p> <p>20 do an apical component with the anterior</p> <p>21 repair, you're absolutely going to have a</p> <p>22 recurrence. So then that's counted as a</p> <p>23 recurrence of the cystocele.</p> <p>24 So that 70 percent success</p>	<p>1 A. It's 10 percent maybe.</p> <p>2 Q. Okay. So if I'm understanding</p> <p>3 what you're saying is the reason that</p> <p>4 there -- and you know there's numbers lower</p> <p>5 than 70 percent reported in the literature</p> <p>6 for native tissue repair recurrence, right?</p> <p>7 A. Yes, but I answered the</p> <p>8 question truthfully on what I thought was --</p> <p>9 Q. No, I'm not quarrelling with</p> <p>10 you.</p> <p>11 The 30 percent recurrence rate</p> <p>12 with anterior repair, you're saying that is</p> <p>13 largely caused because an apical repair isn't</p> <p>14 done at the same time?</p> <p>15 A. Because the patient had a</p> <p>16 combined defect, only one got fixed.</p> <p>17 Q. Now, how about posterior</p> <p>18 repair, what is the recognized recurrence</p> <p>19 rate on a posterior repair, native tissue?</p> <p>20 A. 15 to 20 percent.</p> <p>21 Q. Is that affected at all by</p> <p>22 doing the apical at the same time?</p> <p>23 A. Oh, yes.</p> <p>24 Q. Same deal?</p>

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<p>1 A. And the perineum.</p> <p>2 Q. Now, you said -- is the only</p> <p>3 alternative you talk with patients about is</p> <p>4 native tissue repair?</p> <p>5 A. For the cystocele and</p> <p>6 rectocele.</p> <p>7 Q. Okay. So if you're doing an</p> <p>8 apical repair, are you doing this thing with</p> <p>9 the small piece of mesh?</p> <p>10 A. If I'm doing it abdominally.</p> <p>11 Q. Okay. Is that what you usually</p> <p>12 do?</p> <p>13 A. I do both, vaginally,</p> <p>14 abdominally.</p> <p>15 Q. What I'm trying to figure out</p> <p>16 when you're talking to a patient that has an</p> <p>17 anterior cystocele, do you tell them</p> <p>18 typically, typically, "I'm going to do a</p> <p>19 native tissue repair with respect to the</p> <p>20 anterior prolapse, but we're also doing</p> <p>21 apical repair at the same time"?</p> <p>22 Is that what you say typically?</p> <p>23 A. If it's a distension cystocele,</p> <p>24 so left to right, okay, what we do when we</p>	<p>1 serve?</p> <p>2 A. It's a suspension point so that</p> <p>3 when the vagina tries to evert, it holds it</p> <p>4 in position.</p> <p>5 Q. Is acute or chronic pain a</p> <p>6 potential complication with a native tissue</p> <p>7 repair?</p> <p>8 A. No.</p> <p>9 Q. Or an apical repair of the type</p> <p>10 you described?</p> <p>11 A. No.</p> <p>12 Q. Is acute or chronic pain with</p> <p>13 intercourse a potential complication of a</p> <p>14 native tissue repair or the type of apical</p> <p>15 repair you perform?</p> <p>16 A. Yes, but typically when you do</p> <p>17 native tissue repair, the reason you have</p> <p>18 pain with intercourse is because you made the</p> <p>19 vagina too tight at the opening. So it's a</p> <p>20 consequence of a mismatch between the</p> <p>21 husband's anatomy and the woman's anatomy.</p> <p>22 Q. Okay. Because the surgeon made</p> <p>23 the vagina too small when they did the native</p> <p>24 tissue repair?</p>
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<p>1 fix a distension cystocele, we basically</p> <p>2 just -- you have a piece of canvas across the</p> <p>3 roof, just tighten it up in the middle. All</p> <p>4 that needs is just sutures.</p> <p>5 Q. Okay.</p> <p>6 A. Okay.</p> <p>7 If it has a distension and a</p> <p>8 displacement, you got to pull the top up.</p> <p>9 Otherwise you'll shorten the vagina.</p> <p>10 Q. And the pulling the top up is</p> <p>11 what you use the mesh for?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. And you may do that</p> <p>14 either vaginally or abdominally?</p> <p>15 A. There is a vaginal procedure</p> <p>16 called the sacrospinous which attaches the</p> <p>17 top of the vagina to the sacrospinous</p> <p>18 ligament.</p> <p>19 Q. And you use mesh in connection</p> <p>20 with that?</p> <p>21 A. I use sutures or mesh.</p> <p>22 Q. And what mention -- if you're</p> <p>23 using it either for the ASC or the</p> <p>24 sacrospinous, what function does the mesh</p>	<p>1 A. Yes. Or the skin just got</p> <p>2 pulled together. Sometimes it's a very easy</p> <p>3 fix, you cut the skin, you suture at the</p> <p>4 right angles, outpatient, ten minutes, it's</p> <p>5 fixed.</p> <p>6 Q. Is vaginal scarring a potential</p> <p>7 complication of native tissue repair?</p> <p>8 A. Yes.</p> <p>9 Q. Is infection a potential</p> <p>10 complication with native tissue repair?</p> <p>11 A. Very, very rarely.</p> <p>12 Q. Well, infection is a very rare</p> <p>13 complication with Gynemesh® repair as well,</p> <p>14 true?</p> <p>15 A. No.</p> <p>16 Q. What is the percentage of</p> <p>17 infection with Gynemesh® repair?</p> <p>18 A. Every woman that has an</p> <p>19 exposure has an active infection in that</p> <p>20 tissue.</p> <p>21 Q. Urinary problems of frequency,</p> <p>22 urgency, dysuria, obstruction, retention and</p> <p>23 incontinence, is that a potential</p> <p>24 complication of a native tissue repair?</p>

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<p>1 A. There's a whole list there.</p> <p>2 Q. I thought all of them were. Is</p> <p>3 that not right?</p> <p>4 A. Well, not all of them.</p> <p>5 Q. Well, let's go down them.</p> <p>6 A. Okay.</p> <p>7 Q. Is urinary frequency a</p> <p>8 potential complication of native tissue</p> <p>9 repair?</p> <p>10 A. No.</p> <p>11 Q. Urgency?</p> <p>12 A. No.</p> <p>13 Q. Dysuria?</p> <p>14 A. No.</p> <p>15 Q. Retention?</p> <p>16 A. No.</p> <p>17 Q. Obstruction?</p> <p>18 A. No.</p> <p>19 Q. Incontinence?</p> <p>20 A. Yes.</p> <p>21 Q. Is organ or nerve damage a</p> <p>22 potential complication of native tissue</p> <p>23 repair?</p> <p>24 A. Yes.</p>	<p>1 A. Yes.</p> <p>2 Q. Contraction or shrinkage of</p> <p>3 tissues in connection with scarring, is that</p> <p>4 a potential risk of native tissue repair?</p> <p>5 A. Yes, but only if the surgeon</p> <p>6 removes too much tissue.</p> <p>7 Q. Okay. Now, well, won't you get</p> <p>8 some contraction from scarring even with a</p> <p>9 properly performed native tissue repair?</p> <p>10 A. Not really. The vagina's</p> <p>11 different. If anything, you're going to get</p> <p>12 more relaxation, which is why there's a lower</p> <p>13 percentage rate, if it's not done correctly.</p> <p>14 Q. Do you have an opinion as to</p> <p>15 what the percentage is of erosion or exposure</p> <p>16 with Gynemesh® PS?</p> <p>17 A. No.</p> <p>18 Q. Do you have an opinion as to</p> <p>19 what the percentage of recurrent prolapse is</p> <p>20 with Gynemesh® PS?</p> <p>21 A. It's less than native tissue</p> <p>22 repair, but the number of complications and</p> <p>23 reoperations from mesh problems is much more.</p> <p>24 Q. Okay. We'll break that out.</p>
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<p>1 Q. Bleeding, is that a potential</p> <p>2 complication?</p> <p>3 A. Yes.</p> <p>4 Q. Wound complications?</p> <p>5 A. Yes.</p> <p>6 Q. Inflammation?</p> <p>7 A. Yes.</p> <p>8 Q. Fistula formation?</p> <p>9 A. Yes.</p> <p>10 Q. Pelvic floor neuromuscular</p> <p>11 pain?</p> <p>12 A. Yes.</p> <p>13 Q. Lower extremity pain?</p> <p>14 A. No.</p> <p>15 Q. Is recurrent surgery a</p> <p>16 potential risk of native tissue repair?</p> <p>17 A. Yes.</p> <p>18 Q. Foreign body response from</p> <p>19 sutures, is that a potential complication of</p> <p>20 native tissue repair?</p> <p>21 A. Yes.</p> <p>22 Q. Exposure or erosion of sutures,</p> <p>23 is that a potential complication of native</p> <p>24 tissue repair?</p>	<p>1 What is the -- you said about a</p> <p>2 30 percent recurrence rate with native tissue</p> <p>3 repair is the generally recognized number.</p> <p>4 What is the generally</p> <p>5 recognized figure for recurrence of prolapse</p> <p>6 with Gynemesh®?</p> <p>7 A. A piece of Gynemesh®, right?</p> <p>8 Q. A piece of Gynemesh®?</p> <p>9 A. 25.</p> <p>10 Q. 25 percent?</p> <p>11 A. (Witness nods head.)</p> <p>12 Q. What is it with Prolift®, which</p> <p>13 is made out of Gynemesh®?</p> <p>14 A. 18 to 25.</p> <p>15 Q. Then you said the complications</p> <p>16 are more, right?</p> <p>17 A. Yes.</p> <p>18 Q. That's what I heard in the</p> <p>19 second part of your answer.</p> <p>20 Can you give me any percentages</p> <p>21 as the complications with native tissue</p> <p>22 repair versus the complications with</p> <p>23 Gynemesh® surgery for prolapse?</p> <p>24 A. Would you ask the question</p>

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<p>1 again?</p> <p>2 Q. Yeah.</p> <p>3 You said -- when I asked you</p> <p>4 what the comparative recurrence rates were,</p> <p>5 okay, you said, "Well, the recurrence rates</p> <p>6 are lower with Gynemesh® for prolapse, but</p> <p>7 there's more complications."</p> <p>8 Okay. What I'm trying to do is</p> <p>9 figure out how much more.</p> <p>10 A. Okay.</p> <p>11 Q. So what would you say to that?</p> <p>12 A. So with native tissue repair,</p> <p>13 the main issue is recurrence, which is why</p> <p>14 someone at some point thought let's do what</p> <p>15 we do in abdominal surgery and put a piece of</p> <p>16 mesh in there.</p> <p>17 So what was the question again?</p> <p>18 The --</p> <p>19 Q. How would you compare the risk</p> <p>20 of complications with Gynemesh® used in</p> <p>21 prolapse repair versus complications from</p> <p>22 native tissue repair?</p> <p>23 A. So you have a slightly higher</p> <p>24 recurrence rate with native tissue. You</p>	<p>1 Gynemesh® PS product put in of any kind for</p> <p>2 prolapse, what percentage of them have had</p> <p>3 long-term complications?</p> <p>4 Do you have an opinion on that?</p> <p>5 A. No.</p> <p>6 Q. Okay. Do you have an opinion</p> <p>7 of the percentage of women who have had a</p> <p>8 native tissue repair have had long-term</p> <p>9 complications?</p> <p>10 A. Very rare.</p> <p>11 Q. Okay. And have you done any</p> <p>12 literature review to try to determine what</p> <p>13 the long-term complications are with -- over</p> <p>14 a period of years for women who have had a</p> <p>15 Gynemesh® PS product used for prolapse?</p> <p>16 A. I have.</p> <p>17 Q. Okay. And have you found any</p> <p>18 literature?</p> <p>19 A. There is very little papers</p> <p>20 that talks about pieces of Gynemesh® put in</p> <p>21 anteriorly or posteriorly.</p> <p>22 Q. You're changing my question. I</p> <p>23 said Gynemesh® product.</p> <p>24 Okay. So have you done any</p>
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<p>1 don't have as much contracture. You don't</p> <p>2 have scarification. You don't have a foreign</p> <p>3 body reaction. You don't have a foreign</p> <p>4 piece of mesh in there. The pain with</p> <p>5 intercourse from anterior repair only is</p> <p>6 virtually negligible. If a woman has just an</p> <p>7 anterior repair, rates of pain with</p> <p>8 intercourse from an anterior repair are</p> <p>9 virtually zero.</p> <p>10 If you add anterior -- if you</p> <p>11 add mesh to the anterior vagina, you have a</p> <p>12 slightly higher success rate, but you</p> <p>13 increase your chance of pain with</p> <p>14 intercourse. Exposure rates, 15 percent.</p> <p>15 Maybe higher. And that's in the short term.</p> <p>16 I don't think anyone really</p> <p>17 knows if you get out five years what really</p> <p>18 happens with the bridging fibrosis and the</p> <p>19 stress yielding that that tissue gets thin</p> <p>20 and eventually pops through and then it</p> <p>21 starts the cycle with infection and erosion</p> <p>22 and vaginal discharge.</p> <p>23 Q. So do you have any opinion as</p> <p>24 to what percentage of women that have had a</p>	<p>1 literature search to determine any product</p> <p>2 that uses Gynemesh® in prolapse repair to</p> <p>3 determine what the long-term complications</p> <p>4 are?</p> <p>5 A. Yes.</p> <p>6 Q. Okay. And what have you found?</p> <p>7 A. That the use of Gynemesh® in</p> <p>8 the vagina increases a woman's chance for</p> <p>9 reoperation for complications --</p> <p>10 Q. No, I meant what papers have</p> <p>11 you found. I asked if you had done a</p> <p>12 literature search.</p> <p>13 A. What papers?</p> <p>14 Q. Yeah.</p> <p>15 What papers -- well, let me</p> <p>16 back up.</p> <p>17 Are there any papers in your</p> <p>18 report that address the issue of long-term</p> <p>19 complications with Gynemesh® PS product, any</p> <p>20 Gynemesh® PS product?</p> <p>21 A. No.</p> <p>22 Q. Okay. Do you believe that the</p> <p>23 long-term complications from Gynemesh® PS cut</p> <p>24 out of a sheet are less than the</p>

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<p>1 complications connected with Prolift®?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. How much less?</p> <p>4 A little bit? A lot?</p> <p>5 A. A lot less.</p> <p>6 Q. Okay. Do you have an opinion</p> <p>7 as to the percentage of erosion exposure with</p> <p>8 Gynemesh® PS? Not Prolift®, just Gynemesh®</p> <p>9 PS.</p> <p>10 A. I'm not sure I understand the</p> <p>11 question.</p> <p>12 Q. For Gynemesh® PS used in</p> <p>13 prolapse repair, not Prolift®, just Gynemesh®</p> <p>14 PS cut out of a sheet, do you have an opinion</p> <p>15 as to the percentage of exposures or erosions</p> <p>16 that occur with that?</p> <p>17 A. All the information I have is</p> <p>18 the patients I see. I don't have a</p> <p>19 denominator of how many went in.</p> <p>20 Q. So you don't have a percentage</p> <p>21 globally?</p> <p>22 A. No.</p> <p>23 Q. Okay. Exposures, erosions, can</p> <p>24 they sometimes be asymptomatic?</p>	<p>1 how you deal with these complications. But</p> <p>2 if you're walking on a lake, at the edge of</p> <p>3 the lake it's very thick; you can stand on</p> <p>4 it. As you get towards the middle, the ice</p> <p>5 gets thin. So where it gets thin, you fall</p> <p>6 through.</p> <p>7 As you move back towards the</p> <p>8 edge, it's better. So the only way to</p> <p>9 effectively treat these mesh issues is not in</p> <p>10 the office. It's actually cruel and unusual</p> <p>11 punishment for the woman. It's to take her</p> <p>12 to the operating room and cut that mesh back</p> <p>13 either completely or to a point that the full</p> <p>14 thickness of the fibromuscular wall of the</p> <p>15 vagina is free of mesh. That is the only</p> <p>16 way.</p> <p>17 Q. Can some mesh exposures be</p> <p>18 treated without complete removal of the mesh?</p> <p>19 A. Can the exposure be removed</p> <p>20 that's visible? Yes, but can it be treated?</p> <p>21 No, because of what I just explained.</p> <p>22 Q. So you're saying any time</p> <p>23 there's a mesh exposure, almost all the mesh</p> <p>24 needs to be removed?</p>
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<p>1 A. Yes.</p> <p>2 Q. Can they sometimes be treated</p> <p>3 in the office?</p> <p>4 A. No.</p> <p>5 Q. They can't be treated through a</p> <p>6 procedure in the office?</p> <p>7 A. Well, let me clarify.</p> <p>8 Q. Okay.</p> <p>9 A. You can do that. You can take</p> <p>10 the scissors to an awake woman when the</p> <p>11 second you snip it, it bleeds, but it can't</p> <p>12 be adequately treated and here's why: When</p> <p>13 you have an exposure, what that means is that</p> <p>14 you have a portion of the graft that's in the</p> <p>15 vaginal lumen. A portion of that remaining</p> <p>16 graft as it goes laterally, wherever it goes,</p> <p>17 is covered by a very thin tissue of</p> <p>18 epithelium. The epithelium is not living</p> <p>19 tissue. Even if you trim it back and you</p> <p>20 make it smooth, that implant is still in the</p> <p>21 vaginal wall. The only way, effective way --</p> <p>22 and there's no guidance in any of the</p> <p>23 literature on how to do this or any of the</p> <p>24 internal documents I reviewed or the IFU of</p>	<p>1 A. You have to cut it back.</p> <p>2 Q. It's not what I asked. I'm</p> <p>3 just --</p> <p>4 A. No.</p> <p>5 Q. It doesn't have to all be</p> <p>6 removed?</p> <p>7 A. Yes, it does.</p> <p>8 Q. So any time you have a -- so</p> <p>9 even if you have like a 10-millimeter</p> <p>10 exposure, you should remove all of the mesh?</p> <p>11 A. The way you're asking the</p> <p>12 question, I have to answer yes.</p> <p>13 Q. Okay. Why am I asking it</p> <p>14 wrong?</p> <p>15 A. Because the way I think as a</p> <p>16 surgeon is I want to fix this woman. And the</p> <p>17 way you're asking the question is you want me</p> <p>18 to do the minimal amount to get past it. So</p> <p>19 I'm honestly answering that. The treatments</p> <p>20 that have been set forth in helping these</p> <p>21 women are a problem, which is why all of</p> <p>22 these women have all these issues.</p> <p>23 So, no, it can't -- it can't be</p> <p>24 partially removed.</p>

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<p>1 Q. So if doctors, surgeons out 2 there, if they, after surgery, three months, 3 six months later, have a small, 10-millimeter 4 or so exposure, you're saying that what they 5 should do is remove all of the mesh at that 6 time? 7 A. Yes, I would call that big. I 8 think if there's a couple fibers, you can 9 watch it. There is no evidence whatsoever to 10 suggest that estrogen helps, but maybe if you 11 rub it in there and you promote some blood 12 flow or somehow, it may help with some 13 fibers. 14 But once you have -- it's sort 15 of like a fistula. When you fix a fistula, 16 even though the fistula is 45 millimeters, 17 the defect around it, there's probably 18 another circumference of 3 or 4 millimeters, 19 which is why fistulas fail when you fix them. 20 So if you're only removing that 21 part that's on the thin ice, the example I 22 used on the lake, the woman is going to have 23 a problem because it's in the vaginal wall. 24 So can you leave maybe a little behind? But</p>	<p>1 devastated from what's happened. 2 Q. Well, I didn't ask about the 3 patients you saw. 4 Do you believe in the world are 5 there many patients that have benefitted from 6 Gynemesh® PS being used to treat their 7 prolapse? 8 A. I do not. 9 Q. Okay. Do you believe there's 10 any patients in the world that have 11 benefitted from TVT® being used for their 12 stress urinary incontinence? 13 A. Some, yes. 14 Q. Most, true? 15 A. Based on the patients that are 16 in the -- that have been followed and based 17 on all the data that can be transposed to the 18 world, okay, if you take Ulmsten's data and 19 you take the Oga position paper, the Oga 20 paper that is cited on the back of SUFU and 21 AUGS and you look at the grade of the 22 reports, those patients in those studies, 23 they're not high-grade, quality studies, but 24 there's about 15,000 patients that are</p>
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<p>1 even when you do, it's been my experience in 2 seeing these women that they're going to come 3 back with pain because the edge now is no 4 longer flat. The edge now pokes through the 5 tissue. When the mesh is intact and it's 6 flat, you have a sheet of human tissue over 7 it, it's not poking her. When you cut it, it 8 is like a sawblade poking at her because the 9 fibers are like sutures poking through. 10 Q. Are you aware of any 11 peer-reviewed literature that supports the 12 proposition that regardless of the size of 13 the exposure that all mesh should be removed, 14 if there's an exposure? 15 A. No. 16 Q. Would you agree that there are 17 many patients that have benefitted from 18 Gynemesh® PS being used for prolapse? 19 A. No. 20 Q. Are there any? 21 A. No. 22 Q. Why do you say that? 23 A. It's a very biased view in the 24 patients I see and their lives are totally</p>	<p>1 reported in there. 2 So if you extrapolate all that 3 data, okay, I would agree that 85 percent of 4 the women are cured of their incontinence. 5 What none of us know is what are the 6 long-term consequences. Because when you 7 look at that paper that's cited on the AUGS, 8 SUFU statement position paper and you really 9 read that paper, it actually talks about 10 needing long-term data for mesh implants. 11 Q. And who is the author on that? 12 A. That was Oga. 13 Q. You don't believe there's any 14 safe alternative for the use of mesh -- I 15 mean, there's no safe use of mesh in the 16 vagina for prolapse, true? 17 A. Not the current mesh that we 18 have. 19 Q. Well, you can't identify -- 20 that would be the better way to say it. 21 You can't identify a mesh 22 that's out there on the market that you would 23 consider to be safe for prolapse repair, 24 true?</p>

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<p>1 A. From my reading of the</p> <p>2 documents, I have learned that there is a</p> <p>3 mesh that's better than polypropylene,</p> <p>4 Pronova.</p> <p>5 Q. My question was do you know</p> <p>6 whether it's safe or not?</p> <p>7 A. Based on the information I have</p> <p>8 and the characteristics of the mesh, it's</p> <p>9 safer.</p> <p>10 Q. But that wasn't my question</p> <p>11 whether there was one safer.</p> <p>12 My question is it safe, would</p> <p>13 you use it in the vagina?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. Why?</p> <p>16 What's different about it?</p> <p>17 Who makes Pronova, by the way?</p> <p>18 A. Ethicon.</p> <p>19 Q. What's safer about the Pronova?</p> <p>20 A. So the fibers are completely</p> <p>21 different. When you look at certain</p> <p>22 studies --</p> <p>23 Q. I'm going to have to withdraw</p> <p>24 and interrupt just a second.</p>	<p>1 explanted, the filament doesn't show. The</p> <p>2 filament is cracks, the polypropylene shows.</p> <p>3 I've read documents that says</p> <p>4 that the preparation of the polypropylene</p> <p>5 filament through the stretching and the</p> <p>6 heating creates a core that cools differently</p> <p>7 than the external, which is why the external</p> <p>8 is subjected to cracking. And there's metals</p> <p>9 that are used to stabilize it and peroxidases</p> <p>10 during the inflammatory process start to</p> <p>11 degrade it. It's a vicious cycle which is</p> <p>12 why the chronic reaction occurs.</p> <p>13 Q. Is there any peer-reviewed</p> <p>14 literature establishing Pronova as a good</p> <p>15 product for prolapse repair?</p> <p>16 A. No.</p> <p>17 Q. When you have patients coming</p> <p>18 to you that have had mesh and they're having</p> <p>19 some issues with them, do you always</p> <p>20 recommend an explant of the mesh?</p> <p>21 A. Ask the question again, please?</p> <p>22 Q. Yeah.</p> <p>23 Did you have patients coming to</p> <p>24 you -- you said from all over -- that have</p>
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<p>1 Has Pronova been used for</p> <p>2 prolapse repair successfully in studies?</p> <p>3 A. Hasn't been used.</p> <p>4 Q. Okay. But you believe if it</p> <p>5 was offered to you, you would use it for</p> <p>6 prolapse repair?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. And even though it</p> <p>9 hasn't been proven in any studies?</p> <p>10 A. It hasn't been used -- it's</p> <p>11 been looked at biocompatibility.</p> <p>12 Q. Okay. All right. So briefly</p> <p>13 what is it about that mesh that you believe</p> <p>14 you would use it for prolapse repair?</p> <p>15 A. The long-term inflammation is</p> <p>16 reduced.</p> <p>17 Q. Because?</p> <p>18 A. It's a different chemical.</p> <p>19 It's polyvinylidene fluoride.</p> <p>20 Q. Okay.</p> <p>21 A. And when they -- even Ethicon</p> <p>22 themselves has done testing on it, it is a</p> <p>23 much more stable filament than polypropylene,</p> <p>24 and studies where it's been implanted and</p>	<p>1 had a mesh product implanted in them, do you</p> <p>2 always recommend explanting of the mesh?</p> <p>3 A. No.</p> <p>4 Q. When do you not?</p> <p>5 A. When there's nothing clinically</p> <p>6 that I think I can add by removing it.</p> <p>7 Q. Okay. Do you ever have</p> <p>8 patients come to you who say, "I'm not having</p> <p>9 any problems or much problems, but I would</p> <p>10 still like the mesh taken out"?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. Do you take it out under</p> <p>13 those circumstances?</p> <p>14 A. No.</p> <p>15 Q. Okay. I think there are some</p> <p>16 that do that, that's why I asked.</p> <p>17 What is your charge for an</p> <p>18 explant procedure?</p> <p>19 A. I accept insurance. Whatever</p> <p>20 the insurance pays.</p> <p>21 Q. And how many of those do you do</p> <p>22 each year?</p> <p>23 A. As I mentioned earlier, I've</p> <p>24 narrowed it down. In 2015, I took out 296</p>

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<p>1 implants.</p> <p>2 Q. And before that, it was another</p> <p>3 20 percent or something above that?</p> <p>4 A. I think I hit 400 one year, and</p> <p>5 I decreased the number.</p> <p>6 Q. Have you ever had any nerve</p> <p>7 entrapment in any -- have you ever found any</p> <p>8 nerve entrapment as a part of your explant</p> <p>9 procedures?</p> <p>10 A. Yes.</p> <p>11 Q. Rarely?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. How do you know that</p> <p>14 there's nerve entrapment as you do an explant</p> <p>15 procedure?</p> <p>16 Is that confirmed by pathology,</p> <p>17 or what's your basis for that?</p> <p>18 A. The TVT® sling was attached to</p> <p>19 the obturator nerve directly, and I touched</p> <p>20 the mesh to free it up and the patient's leg</p> <p>21 jumped.</p> <p>22 Q. Was that as a result of a</p> <p>23 surgical technique problem?</p> <p>24 A. It's a result of the IFU and</p>	<p>1 A. The elasticity.</p> <p>2 Q. Bidirectional elasticity to</p> <p>3 some degree remains with the Gynemesh® PS</p> <p>4 when it's put in the body?</p> <p>5 A. Oh, let me change my answer to,</p> <p>6 yes, in the short term.</p> <p>7 Q. Okay. How much Gynemesh® PS is</p> <p>8 used typically -- not Prolift®, just</p> <p>9 Gynemesh® PS, used for a prolapse repair?</p> <p>10 How much is used?</p> <p>11 A. Depends where --</p> <p>12 Q. Anterior.</p> <p>13 A. Anteriorly?</p> <p>14 Depends on the woman's vagina,</p> <p>15 but let's say average of 7 centimeters by 6.</p> <p>16 Q. Okay.</p> <p>17 A. Maybe -- and there's longer and</p> <p>18 wider depending on the bony structure.</p> <p>19 Q. How about posteriorly?</p> <p>20 A. The posterior segment tends to</p> <p>21 be a little longer. 9 by 5.</p> <p>22 Q. The meshes from other companies</p> <p>23 that use -- that are used for prolapse, do</p> <p>24 any of those have bigger pores or lighter</p>
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<p>1 the directions that's given to the surgeon to</p> <p>2 use a large trocar.</p> <p>3 Q. Okay. Was that the only</p> <p>4 occasion you've had a nerve entrapment</p> <p>5 problem?</p> <p>6 A. It's been several times. I</p> <p>7 don't like giving an exact number because I</p> <p>8 don't track all of those things. What I</p> <p>9 track is how much I help patients with what I</p> <p>10 do.</p> <p>11 Q. But that was something -- was</p> <p>12 the nerve -- in the example you gave, was the</p> <p>13 nerve entrapment, did that occur -- was that</p> <p>14 producing symptoms for the patient?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. Now, before the</p> <p>17 Prolift®, when it's -- strike that.</p> <p>18 Gynemesh® PS, Gynemesh® PS has</p> <p>19 bidirectional elasticity, doesn't it?</p> <p>20 A. Yes.</p> <p>21 Q. And it maintains that to some</p> <p>22 degree once it's put in the body, true?</p> <p>23 A. No.</p> <p>24 Q. Not at all?</p>	<p>1 weight?</p> <p>2 A. I want to make sure I</p> <p>3 understand the question.</p> <p>4 Q. Yeah.</p> <p>5 There's other mesh products</p> <p>6 that can be used for prolapse repair, right?</p> <p>7 A. Yes.</p> <p>8 Q. Have any of those had a lighter</p> <p>9 weight or bigger pores than a Gynemesh® PS?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. Which one?</p> <p>12 A. Coloplast is much lighter.</p> <p>13 Q. Okay. And when did that come</p> <p>14 on the market?</p> <p>15 A. I can't tell you the exact</p> <p>16 date. Probably in the last seven, eight</p> <p>17 years.</p> <p>18 Q. What's its gram per meter</p> <p>19 squared?</p> <p>20 What's its weight?</p> <p>21 A. It's -- I think it's 27.</p> <p>22 Q. And what is Gynemesh® PS?</p> <p>23 A. 45.</p> <p>24 Q. Are you familiar with any</p>

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<p>1 peer-reviewed literature that is critical of</p> <p>2 the pore size or weight of Gynemesh® PS?</p> <p>3 A. No.</p> <p>4 Q. Have you ever written in a</p> <p>5 medical record that a patient had clinical</p> <p>6 problems resultant to particle loss or</p> <p>7 degradation?</p> <p>8 A. No.</p> <p>9 Q. Did you review the -- strike</p> <p>10 that.</p> <p>11 I asked you before some</p> <p>12 questions, and I can't remember whether they</p> <p>13 were TVT®-related or not, but have you</p> <p>14 reviewed other warnings information that was</p> <p>15 given to doctors other than the IFU with</p> <p>16 respect to Gynemesh® PS products?</p> <p>17 A. I reviewed everything that was</p> <p>18 given to me. I don't recall specifically at</p> <p>19 this time.</p> <p>20 Q. Do you recall reviewing the</p> <p>21 surgeon's monograph with respect to the</p> <p>22 Gynemesh® PS products?</p> <p>23 A. I don't recall.</p> <p>24 Q. Did you read the Prolift® IFU</p>	<p>1 A. Yes, I have.</p> <p>2 Q. Which against?</p> <p>3 A. Boston Scientific.</p> <p>4 Q. And what product?</p> <p>5 A. Prefyx and Solyx.</p> <p>6 Q. And what are those?</p> <p>7 A. Those are -- one is a</p> <p>8 single-incision sling and the Prefyx --</p> <p>9 Q. Is that like a TVT-Secur?</p> <p>10 A. Different. It has plastic</p> <p>11 arrowheads that attach to the muscles.</p> <p>12 Q. Okay. So which one is that,</p> <p>13 Solyx or Prefyx?</p> <p>14 A. Sorry, the single incision.</p> <p>15 Q. Yes.</p> <p>16 A. Solyx.</p> <p>17 Q. So you've testified as an</p> <p>18 expert witness against the Solyx product?</p> <p>19 A. Yes.</p> <p>20 Q. You said that it is -- never</p> <p>21 should have been on the market?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. And what about Prefyx,</p> <p>24 what kind of product is that?</p>
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<p>1 when you used it that one time?</p> <p>2 A. I did.</p> <p>3 Q. Had you read it since until you</p> <p>4 became involved in this litigation?</p> <p>5 A. I read it again.</p> <p>6 Q. When you became -- that's what</p> <p>7 you mean.</p> <p>8 A. Yes.</p> <p>9 Q. But the gap of years, you</p> <p>10 hadn't read it in between?</p> <p>11 A. I looked at it from time to</p> <p>12 time. I read a lot of IFUs. As I mentioned</p> <p>13 earlier, I own all of the products because I</p> <p>14 have to study them on how they're designed to</p> <p>15 be able to remove them. Elevate's different</p> <p>16 than Apogee and Perigee® and Avaulta®. So I</p> <p>17 do review them from time to time.</p> <p>18 Q. And did you say you have not</p> <p>19 served as an expert witness against any other</p> <p>20 company?</p> <p>21 A. I'm not sure I answered that</p> <p>22 question.</p> <p>23 Q. Okay. Have you?</p> <p>24 I'll ask you again.</p>	<p>1 A. That's a sling.</p> <p>2 Q. Okay. What kind of sling?</p> <p>3 A. Prepubic.</p> <p>4 Q. Okay. Different from</p> <p>5 retropubic?</p> <p>6 A. It's in front.</p> <p>7 Q. Okay. And what's the problem</p> <p>8 with it?</p> <p>9 Well, let me ask you this: On</p> <p>10 both of those products, have you been</p> <p>11 critical of the instrumentation?</p> <p>12 A. Yes.</p> <p>13 Q. Have you been critical of the</p> <p>14 technique described in the IFU?</p> <p>15 A. Yes.</p> <p>16 Q. And have you been critical of</p> <p>17 the design of the material?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. And you don't believe</p> <p>20 either one of those should have been</p> <p>21 marketed?</p> <p>22 A. No.</p> <p>23 Q. Okay.</p> <p>24 A. And they're not on the market.</p>

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<p>1 Q. Okay.</p> <p>2 A. They're gone.</p> <p>3 Q. So is there any sling product</p> <p>4 in the world that -- polypropylene sling</p> <p>5 product in the world that you believe is safe</p> <p>6 in all aspects: Instrumentation, technique,</p> <p>7 and material?</p> <p>8 A. No.</p> <p>9 Q. Is there any polypropylene</p> <p>10 sling product in the world that you believe</p> <p>11 is reasonably safe with respect to the</p> <p>12 material, the mesh material?</p> <p>13 A. No.</p> <p>14 Q. Okay. When do you do an ASC?</p> <p>15 Under what circumstances?</p> <p>16 A. So I'll perform an ASC on a</p> <p>17 patient that is a younger woman, someone that</p> <p>18 has a shortened vagina, someone that has --</p> <p>19 Q. These are alternatives, or they</p> <p>20 have to have all of these things?</p> <p>21 A. No, it's either --</p> <p>22 Q. This or that?</p> <p>23 A. This or that.</p> <p>24 Q. Okay.</p>	<p>1 Q. Okay. Did any doctors at your</p> <p>2 hospital ever use Gynemesh® PS for prolapse</p> <p>3 repair?</p> <p>4 A. I don't think so.</p> <p>5 MR. BALL: Okay. Why don't we</p> <p>6 take a break. I think I'm about</p> <p>7 finished here. I've got to regroup a</p> <p>8 little bit here.</p> <p>9 (Off the record at 1:32 p.m.)</p> <p>10 QUESTIONS BY MR. BALL:</p> <p>11 Q. Doctor, would an experienced</p> <p>12 surgeon before 2005 performing prolapse</p> <p>13 surgery with Gynemesh® PS know that pain with</p> <p>14 intercourse was a possible complication?</p> <p>15 A. Yes.</p> <p>16 Q. Would an experienced surgeon</p> <p>17 before 2010 using Gynemesh® PS for prolapse</p> <p>18 know that vaginal scarring was a possible</p> <p>19 complication?</p> <p>20 A. Yes.</p> <p>21 Q. Would they know that infection</p> <p>22 was a possible complication?</p> <p>23 A. Yes.</p> <p>24 Q. Would they know that urinary</p>
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<p>1 A. Someone who has a job that</p> <p>2 requires heavy lifting. Someone that has</p> <p>3 asthma or bronchitis. Just a more durable</p> <p>4 repair. She needs a more durable repair.</p> <p>5 Q. Was it within the standard of</p> <p>6 care up until 2012 for a surgeon to use</p> <p>7 Gynemesh® PS products in repair of prolapse?</p> <p>8 A. Would you ask the question</p> <p>9 again?</p> <p>10 Q. Yeah.</p> <p>11 Was it within the standard of</p> <p>12 care, the acceptable standard of care, for a</p> <p>13 surgeon to use a Gynemesh® PS product for</p> <p>14 prolapse repair up through 2012?</p> <p>15 A. Yes.</p> <p>16 Q. Was it within the standard of</p> <p>17 care for doctors to use TVT® for SUI, even</p> <p>18 today?</p> <p>19 A. Yes.</p> <p>20 Q. Okay. Did any doctor at your</p> <p>21 hospital ever use TVT®?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. Do some still do today?</p> <p>24 A. I think there might be one.</p>	<p>1 frequency, urgency, dysuria, retention,</p> <p>2 obstruction and incontinence were possible</p> <p>3 complications?</p> <p>4 A. If we could break that question</p> <p>5 up again.</p> <p>6 Q. Yeah.</p> <p>7 Would an experienced surgeon</p> <p>8 before 2010 know that urinary frequency would</p> <p>9 be a possible complication after prolapse</p> <p>10 surgery with Gynemesh® PS?</p> <p>11 A. No.</p> <p>12 Q. What about urgency?</p> <p>13 A. No.</p> <p>14 Q. What about dysuria?</p> <p>15 A. No.</p> <p>16 Q. What about retention?</p> <p>17 A. No.</p> <p>18 Q. So is retention a recognized</p> <p>19 problem with Gynemesh® PS used for prolapse</p> <p>20 surgery?</p> <p>21 A. Depends on how tight you make</p> <p>22 it.</p> <p>23 Q. Is it a potential complication?</p> <p>24 A. Yes.</p>

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<p>1 Q. And that wouldn't have been 2 known as a possible complication before 2010? 3 A. No. 4 Q. Why do you say that? 5 A. I don't think anyone knew 6 exactly what would happen when you put mesh 7 in there. 8 Q. Was incontinence a potential 9 complication? 10 A. Yes. 11 Q. That was known before 2010? 12 A. Yes. 13 Q. Okay. Organ nerve damage, was 14 that a potential complication that was known 15 to experienced surgeons using Gynemesh® PS 16 before 2010? 17 A. Yes. 18 But it's a different kind of 19 nerve damage than -- they would know about it 20 because they have to open the vaginal wall 21 up. 22 What they didn't know was the 23 consequence that would happen, you know, 24 they're cutting the vagina, they're opening</p>	<p>1 thinking about it as a surgeon is I'm going 2 to get scarring from just doing surgery, and 3 I think I answered, yes, that there is 4 scarring from doing that. 5 But if you're asking the 6 question is the scarring the same when 7 putting in the mesh, then the answer is no. 8 Q. No, that's not what I'm asking. 9 A. Okay. 10 Q. They know they're going to 11 create a scar by putting in mesh, right? 12 A. They know they're going to 13 create a scar by doing surgery. 14 Q. And they know that they're 15 going to create -- well, won't there be 16 scarring connected with the implantation of 17 the mesh, right? 18 A. Yes. 19 Q. And wouldn't every experienced 20 surgeon before 2010 know that there will be 21 some contraction connected with the scarring 22 of the mesh surgery? 23 A. No. I didn't know. I didn't 24 know.</p>
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<p>1 it up and we talk about nerve damage, did 2 they know about it. 3 So, yes, they would know about 4 it because they're doing surgery. But what 5 they wouldn't know about is the fact that 6 they're going to put an implant in her that's 7 then going to constrict and change 8 everything. 9 Q. Would an experienced surgeon 10 before 2010 using Gynemesh® -- in and before 11 2010 using Gynemesh® PS for prolapse know 12 that there was a potential of contraction? 13 A. No. 14 Q. Would they know that there was 15 a potential of scar formation? 16 A. Not the kind of scar we're 17 talking about. 18 Q. I'm not talking about degrees. 19 Would they know that there 20 would be some degree of contraction from 21 scarring with the use of Gynemesh® PS, would 22 an experienced surgeon know that before 2010? 23 A. I'm not sure I know how to 24 answer the question. Because the way I'm</p>	<p>1 Q. Before 2010, would an 2 experienced surgeon -- so you're saying at no 3 time versus before 2010 would an experienced 4 surgeon know that there would be the 5 potential for contraction connected with mesh 6 surgery? 7 A. I'm answering that question 8 honestly on what I knew. I don't know what 9 other people knew so I'm answering that 10 question based on what I knew. I was 11 surprised the first time that I had a patient 12 that had a contraction like that. 13 Q. And that was 2010, after 2010? 14 A. I'm not sure exactly when, but 15 around that time frame. When the literature 16 started talking about contraction and mesh 17 exposure and et cetera, it all made sense. 18 Q. Would the average surgeon in 19 2010 and before know that there was a 20 potential of erosion or exposure from mesh, 21 from Gynemesh®, used in prolapse? 22 A. Yes. 23 Q. And would the average surgeon 24 in 2010 or before know that there was a</p>

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<p>1 potential for another surgery after the use 2 of the mesh for prolapse? 3 A. Probably not. 4 Q. Would they know there was the 5 possibility that some mesh might have to be 6 removed? 7 A. I think what they -- no, what 8 they knew is that they were going to apply 9 silver nitrate in the office and put some 10 estrogen on it and that would take care of 11 it, and it didn't. 12 Q. So you don't think the average 13 surgeon knew that a possible complication of 14 using Gynemesh® for prolapse was that there 15 might need to be surgery to remove some of 16 the mesh? 17 A. No. 18 Q. Did the average surgeon in 2010 19 or before know that if they used Gynemesh® 20 for prolapse there might be a recurrent 21 prolapse? 22 A. No. 23 Q. They thought it was going to be 24 100 percent successful?</p>	<p>1 Q. The potential for a chronic 2 foreign body response? 3 A. No. 4 Q. The potential for a failure of 5 the procedure to cure the SUI? 6 A. Yes. 7 Q. The potential for an additional 8 surgery? 9 A. Yes. 10 Q. The potential for some of the 11 mesh to be removed? 12 A. No. 13 Q. And the potential of 14 contraction of the TVT®? 15 A. No. 16 Q. When do you think that doctors 17 became aware of the problems that you've 18 described for us today? 19 When did the medical community 20 become aware of the problems that you've 21 described about TVT® and Gynemesh®? 22 A. After 2011. 23 Q. Okay. And what happened in 24 2011?</p>
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<p>1 A. Oh, they thought it was going 2 to be fantastic. 3 Q. 100 percent? 4 A. Close to it. 100 percent 5 doesn't exist in clinical medicine, but -- 6 Q. Well, I asked did they know 7 that a potential complication was that there 8 would be a recurrent prolapse? 9 A. I don't think they did, no. 10 Q. Okay. Did the average surgeon 11 in 2010 or before know that the -- there was 12 a potential for a long-term foreign body 13 response from the mesh? 14 A. Absolutely not. 15 Q. Did the average surgeon in 2010 16 or before who implanted TVT® know that there 17 was a potential for pain with intercourse? 18 A. No. 19 Q. Did that person know that there 20 was the potential for vaginal scarring? 21 A. No. 22 Q. The potential for erosion or 23 exposure? 24 A. Probably, yes.</p>	<p>1 A. Well, there was the initial FDA 2 announcement that that some of these things 3 might be rare, and then in 2011 when it 4 wasn't rare, and it all just kind of blew up. 5 Q. You said there was the initial 6 announcement. 7 When was that? 8 A. I believe it was 2008. 9 Q. Right. 10 So wasn't there general 11 knowledge in the medical community in 2008 of 12 these problems that I just listed? 13 A. To some degree, but it wasn't 14 really an awareness. I didn't -- I'm 15 answering the question honestly based on what 16 I knew because that's what I know. I'm not 17 sure what other people knew. Maybe there 18 were some that are more alert and smarter 19 than me out there, but I didn't know the 20 extent that all of these problems would exist 21 until after 2011 and especially 2012. 22 I would see patients, and I 23 didn't think it was the mesh either. I 24 didn't really know what to tell them until</p>

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<p>1 all of these announcements happened.</p> <p>2 Q. Your referrals for explants,</p> <p>3 where do they come from?</p> <p>4 A. They are global.</p> <p>5 Q. Let me ask you this, a simpler</p> <p>6 question.</p> <p>7 Do any of your referrals for</p> <p>8 explants come from lawyers, where the</p> <p>9 patients were referred by lawyers to you?</p> <p>10 A. So the short answer is yes</p> <p>11 because these patients ask their lawyers</p> <p>12 where can I get help. So at least in</p> <p>13 St. Louis I am one of the people that can fix</p> <p>14 this. My referrals come from other doctors,</p> <p>15 other patients, other surgeons, that put in</p> <p>16 mesh, urologists, gynecologists, internal</p> <p>17 medicine doctors.</p> <p>18 Q. And lawyers?</p> <p>19 A. Yeah.</p> <p>20 Q. Okay. Do you know what</p> <p>21 percentage of your referral practice comes</p> <p>22 from people involved in litigation?</p> <p>23 A. It's a very small percentage.</p> <p>24 2 percent.</p>	<p>1 be affected by secondary gain?</p> <p>2 A. I'm sure there are, which is</p> <p>3 why when patients show up, if I can't find</p> <p>4 more than one reason -- and I just submitted</p> <p>5 an abstract to the AUGS; it's not accepted</p> <p>6 yet -- very few patients present with a</p> <p>7 single symptom that I've operated on. They</p> <p>8 usually have pain, erosion, failure of the</p> <p>9 device.</p> <p>10 So it's -- I'm not -- I don't</p> <p>11 know if you're implying, maybe you're not,</p> <p>12 but I'm going to answer the question. I'm</p> <p>13 not looking to remove the mesh when there's</p> <p>14 no problem. I put it in. So if it's working</p> <p>15 fine, and I think it's in the best interests</p> <p>16 of the patient to leave it alone, I leave it</p> <p>17 alone.</p> <p>18 But there's a large number of</p> <p>19 patients that truly have problems that don't</p> <p>20 know where to get help. There was a paper by</p> <p>21 I think Shakain and Posen that said many</p> <p>22 years ago that there ought to be referral</p> <p>23 centers.</p> <p>24 Q. Shakitan and Kosan?</p>
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<p>1 Q. Do you ask every one of your</p> <p>2 explant patients whether they're involved in</p> <p>3 a lawsuit?</p> <p>4 A. I do not.</p> <p>5 Q. So how do you have any basis</p> <p>6 for knowing that?</p> <p>7 A. They fill out a little piece of</p> <p>8 paper.</p> <p>9 Q. About referral?</p> <p>10 A. About referral, and it says</p> <p>11 "Attorney."</p> <p>12 Q. Okay. So my question -- I</p> <p>13 appreciate that. My question is a little bit</p> <p>14 different.</p> <p>15 I'm not talking about people</p> <p>16 who are directly referred. I'm asking about</p> <p>17 what percentage of your patients are involved</p> <p>18 in a lawsuit.</p> <p>19 A. I don't know. I don't ask.</p> <p>20 It's really none of my business.</p> <p>21 Q. And you don't ask?</p> <p>22 A. I don't ask.</p> <p>23 Q. Are you familiar with any</p> <p>24 medical principle that complaints of pain can</p>	<p>1 A. Is that how you say his name?</p> <p>2 Okay. There's a bunch of</p> <p>3 papers that I reviewed, and I can't say their</p> <p>4 names. They're not in my reports, but I</p> <p>5 don't know what's on the thumb drive. I</p> <p>6 think I got 52 discs or something like that.</p> <p>7 So that there ought to be places where these</p> <p>8 women can have help.</p> <p>9 So that, to me, was the first</p> <p>10 time that someone recognized that these women</p> <p>11 have legitimate problems, and there is</p> <p>12 nothing anywhere to help guide care for them.</p> <p>13 Q. Tell me about the paper you</p> <p>14 submitted to AUGS.</p> <p>15 A. It's an abstract.</p> <p>16 Q. An abstract.</p> <p>17 A. An abstract.</p> <p>18 Q. And was it based on a study, or</p> <p>19 what's it about?</p> <p>20 A. All it's doing so far -- I</p> <p>21 think it -- after going through this and</p> <p>22 being deposed, I think I will write it up. I</p> <p>23 wasn't planning on it. But all it was was</p> <p>24 looking at how many of these issues are</p>

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<p>1 slings and how many are prolapse kits. 2 That's all it really was looking at, but I'm 3 going to reconsider that. 4 So the vast majority are 5 slings. 6 Q. The vast -- and you told us 7 that earlier in the deposition. 8 A. Okay. 9 Q. The vast majority of your 10 explant procedures are slings? 11 A. Yes, sir. 12 Q. Of various manufacturers? 13 A. Yes. 14 And it's not mentioned who they 15 are in the paper. 16 Q. And you don't know enough about 17 market share and everything to determine 18 whether the TVT® is overrepresented in your 19 practice or not? 20 A. No, but I'm going to see if I 21 can learn. 22 Q. Would you say that a warning is 23 adequate if it gives a doctor sufficient 24 information to counsel patients and make a</p>	<p>1 related to any kind of vaginal surgery from 2 any manufacturer that gives percentages of 3 complications? 4 A. Unfortunately, none do. 5 Q. Okay. So these photographs 6 that are in your Gynemesh® report, which is 7 Exhibit 3, what is the significance of those 8 photographs? 9 They're at page 7, et cetera. 10 7 and 8. 11 A. So it shows the bunching, the 12 rolling, the cording, the excessive 13 scarification of the mesh once it's placed. 14 It doesn't -- 15 Q. So let's take the photograph on 16 page 8. 17 Tell me what that's showing, 18 photographs. 19 A. I have page 7, want me to go to 20 page 8? 21 Q. Yeah. 22 A. So it's showing a section of 23 Gynemesh® that's been explanted. It's been 24 cut in the middle and where the surgeon cut</p>
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<p>1 surgical decision? 2 A. Would you repeat that? 3 Q. Yeah. 4 Would you say a warning is 5 adequate if it gives the doctor sufficient 6 information to counsel patients and make a 7 surgical decision? 8 A. If it gives adequate 9 information? 10 Q. No, gives sufficient 11 information is what I meant to say. 12 You said in here sometimes the 13 warnings are inadequate? 14 A. Yes. 15 Q. You've said that. So I'm 16 trying to get your definition of what 17 inadequate is. Maybe I'll just ask that. 18 What's your definition of an 19 adequate warning? 20 A. Percentages, how often does it 21 happen, what's the severity. 22 Q. Of complications? 23 A. Yes, how is it addressed. 24 Q. Are you aware of any warnings</p>	<p>1 it in a square, it has folded and corded near 2 the lateral edges. 3 Q. Okay. And maybe we will use 4 Jim's color ones. 5 Show me what you're talking 6 about. 7 A. See how it's folded and rolled 8 right there? Are we looking at the right 9 one? 10 Q. Yeah. Well, I'm not seeing any 11 folding. 12 So that's the mesh folding and 13 rolling on the top picture on page 8? 14 A. Yes. And it can't been seen 15 easily because it's encased in scar tissue 16 and tissue. It's not a single flat layer. 17 Q. I can't tell that, but if I'm 18 assuming -- 19 A. Compare it to the picture below 20 it. 21 Q. Okay. Which is what? 22 A. It's another -- it's the piece 23 of Gynemesh® from the above picture in closer 24 magnification. You see how it's nice and</p>

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<p>1 flat and the edge here is rolled?</p> <p>2 Q. I'm not being difficult. I</p> <p>3 don't see it, but I wanted to hear what you</p> <p>4 had to say about it so I've heard that.</p> <p>5 I appreciate it.</p> <p>6 A. Okay.</p> <p>7 Q. You say on page 10 --</p> <p>8 A. If I could interrupt for a</p> <p>9 second, a better page to represent the</p> <p>10 folding is on page 7.</p> <p>11 Q. Okay.</p> <p>12 A. On this one, maybe you can see</p> <p>13 it a little bit better, it's a lot thicker.</p> <p>14 See, it's thicker?</p> <p>15 Can you see the edges?</p> <p>16 Q. I see it's thicker. I guess</p> <p>17 that just meant more tissue came with it.</p> <p>18 A. No. My technique is such that</p> <p>19 it scrapes it off and it's folded.</p> <p>20 I'm sure I have the picture</p> <p>21 laterally head-on.</p> <p>22 Q. So what you're saying in all of</p> <p>23 these photographs what we're seeing is almost</p> <p>24 totally mesh, not tissue?</p>	<p>1 A. I didn't do a calculation on</p> <p>2 the percentage, no.</p> <p>3 Q. How would Ethicon be able to</p> <p>4 determine the percentage of complications?</p> <p>5 You said a warning to be</p> <p>6 adequate needed to give the percentage of the</p> <p>7 potential complications such as erosion and</p> <p>8 nerve damage and --</p> <p>9 A. Yes.</p> <p>10 Q. -- contraction, et cetera.</p> <p>11 How would Ethicon determine the</p> <p>12 percentages to put in an IFU?</p> <p>13 A. What they would have had to do</p> <p>14 when all of this -- when these products</p> <p>15 started is very similar to what's given to a</p> <p>16 patient that has a pacemaker, a card. Each</p> <p>17 of those cards is registered with the company</p> <p>18 so the company knows how many implants went</p> <p>19 in. That patient carries that card and if</p> <p>20 there's a complication, the patient calls a</p> <p>21 number to report these complications and then</p> <p>22 the patient is seen by a doctor to confirm</p> <p>23 that.</p> <p>24 Q. Well, that process would have</p>
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<p>1 A. Yes.</p> <p>2 Q. Okay. That might have been my</p> <p>3 misunderstanding.</p> <p>4 A. Yes.</p> <p>5 Q. So if they're thicker, if the</p> <p>6 piece is thicker in the photograph, it's</p> <p>7 thicker because the mesh has rolled over is</p> <p>8 what you're saying; not thicker because it</p> <p>9 happens to have more tissue connected with</p> <p>10 it?</p> <p>11 A. Correct. If I did that, I</p> <p>12 would be removing the woman's rectum and</p> <p>13 bladder.</p> <p>14 Q. Go to page 10 of your Gynemesh®</p> <p>15 report, it says in the middle of the page,</p> <p>16 "The Gynemesh® PS contains pore sizes much</p> <p>17 smaller than the necessary 1 millimeter."</p> <p>18 A. Yes.</p> <p>19 Q. This gets to the variable pore</p> <p>20 size you were talking about before?</p> <p>21 A. Yes.</p> <p>22 Q. Do you know what percentage of</p> <p>23 them are smaller than 1 millimeter, and what</p> <p>24 percentage are larger?</p>	<p>1 taken years in order to get reliable</p> <p>2 percentages of complications, true?</p> <p>3 A. Yes, but the company should</p> <p>4 have done a project like that prior to</p> <p>5 releasing it to the average surgeon.</p> <p>6 Q. So how many patients would have</p> <p>7 had to have Prolift® put in at the clinical</p> <p>8 trial stage before the product went on the</p> <p>9 market in order to get reliable percentages</p> <p>10 of complications in your view?</p> <p>11 A. 500.</p> <p>12 Q. Other than pacemakers, do you</p> <p>13 know of any other product that used the kind</p> <p>14 of procedure you just described?</p> <p>15 A. Yes. I believe you mentioned</p> <p>16 your daughter works in the ICU. So when</p> <p>17 someone comes in with a neurovascular injury</p> <p>18 and needs a coil, those patients get a little</p> <p>19 card that lets them know that they have coils</p> <p>20 in, et cetera, stents, filters.</p> <p>21 Q. Is the Gynemesh® PS any more</p> <p>22 stiff and inflexible than other kinds of</p> <p>23 meshes used for prolapse?</p> <p>24 A. It's less stiff than some, and</p>

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<p>1 more stiff than others.</p> <p>2 Q. But I think your view is</p> <p>3 they're all too stiff and inflexible?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. Now, back to our report</p> <p>6 on -- the clinical reports at pages 21 and</p> <p>7 22, those are footnoted at footnotes 34, kind</p> <p>8 of like through 30 -- through 39 of your</p> <p>9 report, right?</p> <p>10 A. Yes.</p> <p>11 Q. Do you believe that you gave a</p> <p>12 fair and balanced representation of the</p> <p>13 findings of those reports?</p> <p>14 A. I do.</p> <p>15 Q. Okay. Now, did those reports</p> <p>16 have conclusions in them?</p> <p>17 A. Some did, yes.</p> <p>18 Q. Okay. Did you cite the</p> <p>19 conclusions in your report?</p> <p>20 A. I didn't cite the exact</p> <p>21 conclusion. What I do is I review everything</p> <p>22 that's available, and I abstract the</p> <p>23 information and --</p> <p>24 Q. So did the people that prepared</p>	<p>1 study reach that conclusion?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. They reached that same</p> <p>4 conclusion?</p> <p>5 A. Yes.</p> <p>6 There were serious adverse</p> <p>7 events. They had to distinguish between</p> <p>8 transvaginal mesh and what was Prolift®. So</p> <p>9 they didn't even met their success rate.</p> <p>10 Even though they had a success rate of</p> <p>11 20 percent, they were, I believe, 18.5, they</p> <p>12 were really close to not being as successful</p> <p>13 as they wanted.</p> <p>14 Q. Well, you quoted a number of</p> <p>15 pieces of data in here.</p> <p>16 Why did you not quote the</p> <p>17 specific conclusion from the people that did</p> <p>18 the study?</p> <p>19 A. I thought I summarized it to</p> <p>20 the best of my ability everything that was</p> <p>21 available to me. There's so many reports, so</p> <p>22 many papers --</p> <p>23 Q. I'm talking about these reports</p> <p>24 that you quoted specifically.</p>
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<p>1 those reports -- you've written in here that</p> <p>2 the study demonstrated that the mesh was not</p> <p>3 an effective prolapse treatment and presented</p> <p>4 unreasonable risks?</p> <p>5 A. Yes.</p> <p>6 Q. Was that the conclusion of the</p> <p>7 study?</p> <p>8 A. On the conclusion by Karram,</p> <p>9 Maher on posterior vaginal wall prolapse,</p> <p>10 absolutely.</p> <p>11 Q. No, I'm saying the conclusion</p> <p>12 of the study that's referenced at footnote</p> <p>13 34.</p> <p>14 A. So I was looking at the wrong</p> <p>15 one. So footnote 34 --</p> <p>16 Q. Footnote 34 is the clinical</p> <p>17 study report.</p> <p>18 A. Yes.</p> <p>19 Q. And you cite data from the</p> <p>20 clinical study report, and you say your</p> <p>21 conclusion was that the mesh was not</p> <p>22 effective prolapse treatment and presented</p> <p>23 unreasonable risks.</p> <p>24 Did the people who did this</p>	<p>1 Why did you not quote the</p> <p>2 conclusion of the report?</p> <p>3 You quoted the data, but you</p> <p>4 didn't quote the conclusion.</p> <p>5 Why is that?</p> <p>6 A. At the time I thought that was</p> <p>7 the most important piece of information that</p> <p>8 I placed in the report.</p> <p>9 Q. When you're giving your</p> <p>10 opinions as to whether the IFU adequately --</p> <p>11 for the Gynemesh® PS and TVT® provides an</p> <p>12 adequate warning of the risks and</p> <p>13 complications, are you basing that on your</p> <p>14 own opinions and experience?</p> <p>15 A. I'm basing it on the totality</p> <p>16 of everything that was known from the</p> <p>17 internal documents at Ethicon, all the</p> <p>18 material that was available to me, and</p> <p>19 knowing what's in the IFU, knowing what the</p> <p>20 company knew that they didn't include and my</p> <p>21 own experience.</p> <p>22 Q. Is there any objective standard</p> <p>23 that you are applying in determining whether</p> <p>24 the warnings were adequate?</p>

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<p>1 A. Yes.</p> <p>2 Q. What's the objective standard?</p> <p>3 A. If, for example, it's mentioned</p> <p>4 repeatedly in the internal documents for a</p> <p>5 very long time that there's a problem with</p> <p>6 the product, and they're not including it,</p> <p>7 that's not a fair representation of</p> <p>8 truthfulness of what's wrong with the product</p> <p>9 or not.</p> <p>10 Q. What's the objective standard</p> <p>11 you're applying in reaching that conclusion?</p> <p>12 A. I'm not sure I understand the</p> <p>13 question then.</p> <p>14 Q. Well, then sometimes they're</p> <p>15 like FDA regulations, there's industry</p> <p>16 standards.</p> <p>17 Is there any kind of standard</p> <p>18 you can point to and say, "This is the</p> <p>19 standard that should have been applied to the</p> <p>20 warning," and they didn't meet it?</p> <p>21 A. Yeah, Ethicon's own -- where it</p> <p>22 says our credo is to take care of our</p> <p>23 doctors, our nurses and our patients. They</p> <p>24 had an obligation if they knew that these</p>	<p>1 Q. Okay. Now, all of the</p> <p>2 materials that you reviewed in this matter</p> <p>3 were sent to you by the lawyers for the</p> <p>4 plaintiffs?</p> <p>5 A. Yes.</p> <p>6 Q. Okay.</p> <p>7 A. 52 discs.</p> <p>8 MR. BALL: And they're all in</p> <p>9 the CD, all 52 of them; is that right?</p> <p>10 MR. MATTHEWS: It's what my</p> <p>11 paralegal says. I promise -- I have</p> <p>12 not looked at it to verify that.</p> <p>13 QUESTIONS BY MR. BALL:</p> <p>14 Q. Did you ask the lawyers whether</p> <p>15 there were any other documents or depositions</p> <p>16 other than what they gave you?</p> <p>17 A. I don't think I did.</p> <p>18 Q. And did you do any research of</p> <p>19 your own into the medical literature</p> <p>20 independent from the medical papers they gave</p> <p>21 you?</p> <p>22 A. Yes, I did.</p> <p>23 Q. And how did you do that?</p> <p>24 A. I subscribe to -- I'm a member</p>
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<p>1 meshes had biodegradable components and they</p> <p>2 knew it, and they have a credo that says</p> <p>3 we're going to take care of our doctors, our</p> <p>4 nurses and our patients, and they put it in,</p> <p>5 I think that's a very objective way of saying</p> <p>6 they knew about it, and they didn't disclose</p> <p>7 it.</p> <p>8 Q. You do not rely upon internal</p> <p>9 company documents in making decisions for</p> <p>10 your patients, true?</p> <p>11 A. I don't get -- no, I don't have</p> <p>12 internal document access.</p> <p>13 Q. Right.</p> <p>14 And other than the Boston</p> <p>15 Scientific products you've mentioned, other</p> <p>16 than the two Ethicon products here, are there</p> <p>17 any other products you've been engaged upon</p> <p>18 to testify about?</p> <p>19 A. I've been deposed as an expert</p> <p>20 on those two products we've talked about.</p> <p>21 Q. Plus the two today?</p> <p>22 A. Yes.</p> <p>23 Q. And that's it?</p> <p>24 A. Yes.</p>	<p>1 of the International Gynecologists</p> <p>2 Association, so I went on the website and I</p> <p>3 put in keywords searching the Blue Journal,</p> <p>4 International Journal of Urogynecology. I</p> <p>5 did the same for the American Journal of</p> <p>6 OB/GYN. I did the same for Obstetrics and</p> <p>7 Gynecology. And then I asked my librarian to</p> <p>8 do a search, and I asked her to do a search</p> <p>9 for "Gynemesh®" and "TVT®."</p> <p>10 Q. Okay. Did you come up with any</p> <p>11 papers that were different or additional to</p> <p>12 what the lawyers had given you?</p> <p>13 A. There were some different ones,</p> <p>14 but when I looked at them, I didn't really</p> <p>15 think that they added -- either had bias,</p> <p>16 they were either employees of Ethicon, or</p> <p>17 they were -- the studies were funded by</p> <p>18 Ethicon or there were weaknesses in the</p> <p>19 methodology so I didn't use them.</p> <p>20 Q. So your opinion that there is</p> <p>21 no reasonably safe mesh product for SUI,</p> <p>22 would you agree that there's a large body of</p> <p>23 published peer-reviewed literature that runs</p> <p>24 counter to that opinion?</p>

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<p>1 A. I do.</p> <p>2 Q. Okay.</p> <p>3 A. But here's what else I know:</p> <p>4 Everyone understands, clinicians, doctors,</p> <p>5 companies, that we need lightweight,</p> <p>6 macroporous mesh. And they've done wonders</p> <p>7 to try to conduct research on that. There is</p> <p>8 a paper by Mowali that even says that the</p> <p>9 current Gynemesh® PS when placed in rhesus</p> <p>10 monkeys not only doesn't help, it's</p> <p>11 detrimental to the vagina of a rhesus monkey,</p> <p>12 which is probably the best paper out there</p> <p>13 because it's not a pig, it's not a cow, it's</p> <p>14 not skid. It's the closest to the human</p> <p>15 vaginal tissue as possible. Not only does it</p> <p>16 not help, it's detrimental. Every aspect of</p> <p>17 healing is impaired by Gynemesh® PS.</p> <p>18 So everyone knows that we need</p> <p>19 lighter weight meshes, and yet every single</p> <p>20 company, including Ethicon, continues to use</p> <p>21 a sling that's 100 grams per meter squared.</p> <p>22 MR. BALL: Okay. I'll just</p> <p>23 have to move to strike everything</p> <p>24 after the words "I do."</p>	<p>1 reliable?</p> <p>2 A. They have bias to them.</p> <p>3 Q. I didn't ask that.</p> <p>4 Are they automatically not</p> <p>5 reliable?</p> <p>6 A. Sometimes, yes.</p> <p>7 Q. All of them?</p> <p>8 A. I wouldn't say all of them.</p> <p>9 Q. There's a lot of good</p> <p>10 scientific data that's produced by studies</p> <p>11 funded by companies, true?</p> <p>12 A. Some.</p> <p>13 Q. Would you agree that your</p> <p>14 opinion that there is no safe TVT® -- strike</p> <p>15 that.</p> <p>16 Would you agree that your</p> <p>17 opinion that TVT® was so unsafe it never</p> <p>18 should have been on the market is not</p> <p>19 generally accepted in the scientific medical</p> <p>20 community? You agree with that?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. So did you automatically</p> <p>23 not consider any study that had any funding</p> <p>24 from Ethicon?</p>
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<p>1 QUESTIONS BY MR. BALL:</p> <p>2 Q. Would you agree that the</p> <p>3 general scientific consensus is not in line</p> <p>4 with your opinion that there is no reasonably</p> <p>5 safe polypropylene sling for use with SUI?</p> <p>6 A. No.</p> <p>7 Q. That's not the general</p> <p>8 consensus, true?</p> <p>9 A. I don't think it's a general</p> <p>10 consensus.</p> <p>11 Q. Okay. Thank you.</p> <p>12 Can you tell me -- if you saw</p> <p>13 studies and decided not cite them in your</p> <p>14 reports, can you tell me what criteria you</p> <p>15 used to what was cited in the report and what</p> <p>16 wasn't?</p> <p>17 A. Number of patients, follow-up,</p> <p>18 if the report was done by someone that I</p> <p>19 identified in my reading as an employee of</p> <p>20 Ethicon or if the study was funded by</p> <p>21 Ethicon. Those have a lot of bias to them.</p> <p>22 Q. Well, are you saying that</p> <p>23 studies funded by a company in which</p> <p>24 companies participate are automatically not</p>	<p>1 A. I considered it.</p> <p>2 Q. Did you automatically not cite</p> <p>3 in your report any study if it had funding</p> <p>4 from Ethicon?</p> <p>5 A. No.</p> <p>6 Q. You didn't cite it?</p> <p>7 A. No, and that's not the question</p> <p>8 I'm answering.</p> <p>9 Q. I am sorry.</p> <p>10 You still would include it in</p> <p>11 your report although it might have been</p> <p>12 funded by Ethicon?</p> <p>13 A. If I thought it had merit, I</p> <p>14 would have.</p> <p>15 Q. Okay. And so you're saying any</p> <p>16 of the -- you remember we went through some</p> <p>17 long-term studies with respect to both</p> <p>18 Gynemesh® PS products and TVT®.</p> <p>19 Do you remember that?</p> <p>20 A. Yes.</p> <p>21 Q. And you didn't cite any of</p> <p>22 those in your report?</p> <p>23 A. So one of them I don't</p> <p>24 recognize --</p>

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<p>1 Q. Let me finish the question.</p> <p>2 A. Okay.</p> <p>3 Q. You did not cite any studies</p> <p>4 giving long-term results on either Gynemesh®</p> <p>5 PS products or TVT®, true?</p> <p>6 A. Correct.</p> <p>7 Q. Okay. And are you saying that</p> <p>8 none of those were reliable studies?</p> <p>9 A. When I assess them, I did not</p> <p>10 think that they had the merit that I wanted</p> <p>11 to use them in my report.</p> <p>12 Q. And what was your basis for</p> <p>13 that?</p> <p>14 What was non-meritorious about</p> <p>15 them?</p> <p>16 A. I can't remember the specifics</p> <p>17 of each report, but it had to do with either</p> <p>18 follow-up, for example, the Nilsson 17-year</p> <p>19 study. I mean, I could do the calculations,</p> <p>20 but the percentages are off, and half those</p> <p>21 patients were lost to follow-up. So you</p> <p>22 can't know whether the other half are doing</p> <p>23 well or not doing well.</p> <p>24 Q. We talked about that one.</p>	<p>1 valid study?</p> <p>2 A. It was not a good study,</p> <p>3 correct.</p> <p>4 Q. Okay. And those studies were</p> <p>5 all peer-reviewed, and some of them were</p> <p>6 published in esteemed journals, true?</p> <p>7 A. They're peer-reviewed.</p> <p>8 Q. What do you consider to be the</p> <p>9 kind of first tier journals in your field?</p> <p>10 A. The ones I looked at,</p> <p>11 Obstetrics and Gynecology, the American</p> <p>12 Journal of OB/GYN, International</p> <p>13 Urogynecology Journal, Journal of Urology.</p> <p>14 Q. What about the New England</p> <p>15 Journal of Medicine?</p> <p>16 A. Oh, yes.</p> <p>17 Q. Any others? I just thought of</p> <p>18 that one.</p> <p>19 A. Yeah, it's a good one.</p> <p>20 I think I have that one in</p> <p>21 there, don't I?</p> <p>22 Q. How about JAMA?</p> <p>23 A. JAMA doesn't really have a lot</p> <p>24 of pelvic floor papers, but I did include</p>
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<p>1 What about any other studies?</p> <p>2 I want to know other studies</p> <p>3 that you say you considered that were</p> <p>4 long-term follow-up, a year or more, for</p> <p>5 either Gynemesh® or TVT®, and you</p> <p>6 disregarded -- and you decided not to include</p> <p>7 them in your report.</p> <p>8 A. There's thousands of papers.</p> <p>9 Q. That were long term?</p> <p>10 A. There's thousands of papers</p> <p>11 overall, and I looked at everything that I</p> <p>12 had available to me, and I put it in my</p> <p>13 report.</p> <p>14 Q. If you thought it was -- I know</p> <p>15 that.</p> <p>16 You didn't put -- you looked at</p> <p>17 what you had available to you. You made a</p> <p>18 decision about what to put in your report.</p> <p>19 What I'm trying to explore is how you made</p> <p>20 that decision, and I guess what I'm hearing</p> <p>21 is that if it isn't in your report and -- it</p> <p>22 was a long-term study, okay, about TVT® or</p> <p>23 Gynemesh® PS products and it's not in your</p> <p>24 report, then you considered it not to be a</p>	<p>1 Richter's multi-center trial on Thomas that</p> <p>2 was published in the New England Journal.</p> <p>3 Q. When you do an explant, does</p> <p>4 your operative report record what specific</p> <p>5 product it was?</p> <p>6 A. No.</p> <p>7 Q. Okay. It doesn't say TVT®</p> <p>8 versus Prolift® or something else?</p> <p>9 A. My reports are very bland.</p> <p>10 They don't point fault at the surgeon or the</p> <p>11 company, but based on some of the questions</p> <p>12 that you've asked me today, I think I may</p> <p>13 change my op reports. I don't put in there</p> <p>14 where the company is from, how much I</p> <p>15 removed. My goal in my operative report is</p> <p>16 to take care of the patient.</p> <p>17 Q. Do you record in your report</p> <p>18 whether it's mechanical-cut mesh or laser-cut</p> <p>19 mesh?</p> <p>20 A. I do not, but I have the</p> <p>21 implant --</p> <p>22 Q. Don't feel obligated to change</p> <p>23 any of your practices based on my questions.</p> <p>24 A. Oh, I'm absolutely going to.</p>

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<p>1 There's an education to these questions</p> <p>2 sometimes. So what I've tried not to do is</p> <p>3 throw companies or patients under the bus or</p> <p>4 doctors in the -- I didn't mean patients --</p> <p>5 doctors or companies under the bus in my op</p> <p>6 notes. They're very bland. This is what I</p> <p>7 did; this is what I got out. The pathology</p> <p>8 report documents what I removed. I have the</p> <p>9 implant log, I can go back and look it up,</p> <p>10 but I will add more information to my op</p> <p>11 notes.</p> <p>12 Q. Is chronic inflammation more in</p> <p>13 the area of pathology than it is your area?</p> <p>14 A. Chronic inflammation is a</p> <p>15 pathologic diagnosis, but it's manifested</p> <p>16 with clinical symptoms.</p> <p>17 Q. You can have a chronic foreign</p> <p>18 body reaction and not have any clinical</p> <p>19 symptoms, true?</p> <p>20 A. That's true.</p> <p>21 Q. Okay. In fact, it's not at all</p> <p>22 uncommon if people have a foreign body put in</p> <p>23 their body permanently, then they often have</p> <p>24 a permanent foreign body reaction, true?</p>	<p>1 Q. What's the author's name?</p> <p>2 A. Last name is Mary, M-a-r-y.</p> <p>3 Q. Are you aware of any paper that</p> <p>4 related to either TVT® or Gynemesh® PS or any</p> <p>5 other type of sling or prolapse product that</p> <p>6 says there's a chronic foreign body reaction</p> <p>7 that produces chronic, long-term</p> <p>8 inflammation?</p> <p>9 A. Yes, Clavé paper.</p> <p>10 Q. Anything else?</p> <p>11 A. Not that I think of at this</p> <p>12 time.</p> <p>13 Q. Is the Clavé paper referenced</p> <p>14 in your report?</p> <p>15 A. I think it is.</p> <p>16 Q. Can you just -- let's just make</p> <p>17 that the last thing we do.</p> <p>18 Can you find your reference to</p> <p>19 the Clavé paper, please, in your report?</p> <p>20 Here it is. I don't believe</p> <p>21 it's -- based on my review, I don't believe</p> <p>22 it's in the Gynemesh® PS report.</p> <p>23 Well, I don't see it.</p> <p>24 Do you see it?</p>
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<p>1 A. No.</p> <p>2 Q. Of some degree?</p> <p>3 A. Maybe of some degree, but not</p> <p>4 of a large degree.</p> <p>5 Q. Right. That was my point.</p> <p>6 When you have a foreign body</p> <p>7 put in your body, you often -- the body often</p> <p>8 has a chronic foreign body reaction, but that</p> <p>9 may or may not produce symptoms, true?</p> <p>10 A. Yes.</p> <p>11 Q. Okay.</p> <p>12 A. In the case of polypropylene</p> <p>13 with the fibrillations and the cracking, it</p> <p>14 continues to perpetuate the chronic</p> <p>15 inflammatory response.</p> <p>16 Q. Now, are you aware of any paper</p> <p>17 published, peer-reviewed paper, that says</p> <p>18 that, that polypropylene in the body produces</p> <p>19 a long-term foreign body reaction that</p> <p>20 produces long-term inflammation?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. What paper is that?</p> <p>23 A. Mary, 1998. She did it. She</p> <p>24 placed polypropylene suture in mongrel dogs.</p>	<p>1 A. How could I forget to put that</p> <p>2 in there?</p> <p>3 Q. Let's just get a final answer,</p> <p>4 and I'll conclude the deposition.</p> <p>5 MR. MATTHEWS: I've got a</p> <p>6 couple questions.</p> <p>7 QUESTIONS BY MR. BALL:</p> <p>8 Q. Okay. Would you agree that the</p> <p>9 Clavé paper is not cited in either of your</p> <p>10 reports in this case?</p> <p>11 A. I would have to agree with you.</p> <p>12 MR. BALL: I have reached my</p> <p>13 time limit and, therefore, I have no</p> <p>14 further questions, subject to whatever</p> <p>15 gets brought up now by Mr. Matthews.</p> <p>16 CROSS EXAMINATION</p> <p>17 QUESTIONS BY MR. MATTHEWS:</p> <p>18 Q. Dr. Veronikis, is the</p> <p>19 preparation of the Rule 26 report different</p> <p>20 from a paper that you would write for a</p> <p>21 peer-reviewed medical journal?</p> <p>22 A. The process?</p> <p>23 Q. Yes.</p> <p>24 A. Well, the process is different,</p>

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Dionysios K. Veronikis, M.D.

<p style="text-align: right;">Page 294</p> <p>1 but the methodology is similar.</p> <p>2 Q. Explain what you mean.</p> <p>3 A. Well, you go through the</p> <p>4 process of looking at papers and looking at</p> <p>5 documents. What's different is that with the</p> <p>6 Rule 26 report, I have corporate documents</p> <p>7 and depositions and et cetera that you don't</p> <p>8 normally have when you write a scientific</p> <p>9 paper.</p> <p>10 On a scientific paper, you also</p> <p>11 have research that you're conducting and</p> <p>12 considering, but the actual methodology of,</p> <p>13 you know, coming to a conclusion is the same;</p> <p>14 you take all of the data that's provided, and</p> <p>15 you weigh in what you have at hand, and you</p> <p>16 come up with a decision.</p> <p>17 Q. When you're doing a Rule 26</p> <p>18 report, would I be correct that you're giving</p> <p>19 your professional opinion?</p> <p>20 A. Yes, it's my professional</p> <p>21 opinion.</p> <p>22 MR. MATTHEWS: I don't have</p> <p>23 another question, but I see Clavé on</p> <p>24 footnote 29 on the TVT®.</p>	<p style="text-align: right;">Page 296</p> <p>1 CERTIFICATE</p> <p>2</p> <p>3 I, CARRIE A. CAMPBELL, Registered</p> <p>4 Merit Reporter, Certified Realtime Reporter</p> <p>5 and Certified Shorthand Reporter, do hereby</p> <p>6 certify that prior to the commencement of the</p> <p>7 examination, Dionysios K. Veronikis, M.D. was</p> <p>8 duly sworn by me to testify to the truth, the</p> <p>9 whole truth and nothing but the truth.</p> <p>10 I DO FURTHER CERTIFY that the</p> <p>11 foregoing is a verbatim transcript of the</p> <p>12 testimony as taken stenographically by and</p> <p>13 before me at the time, place and on the date</p> <p>14 hereinbefore set forth, to the best of my</p> <p>15 ability.</p> <p>16</p> <p>17 I DO FURTHER CERTIFY that I am</p> <p>18 neither a relative nor employee nor attorney</p> <p>19 nor counsel of any of the parties to this</p> <p>20 action, and that I am neither a relative nor</p> <p>21 employee of such attorney or counsel, and</p> <p>22 that I am not financially interested in the</p> <p>23 action.</p> <p>24</p> <p>_____ CARRIE A. CAMPBELL, NCRA Registered Merit Reporter Certified Realtime Reporter California Certified Shorthand Reporter #13921 Missouri Certified Court Reporter #859 Illinois Certified Shorthand Reporter #084-004229 Texas Certified Shorthand Reporter #9328 Notary Public Dated: May 4, 2016</p>
<p style="text-align: right;">Page 295</p> <p>1 MR. BALL: Well, let's look at</p> <p>2 that.</p> <p>3 MR. MATTHEWS: It's actually</p> <p>4 referenced in an Ethicon document</p> <p>5 that's cited in footnote 29. So it's</p> <p>6 on page -- about the middle of</p> <p>7 page 21.</p> <p>8 REDIRECT EXAMINATION.</p> <p>9 QUESTIONS BY MR. BALL:</p> <p>10 Q. So just so we're clear, you</p> <p>11 don't cite the Clavé paper or discuss the</p> <p>12 Clavé paper in the body of the report, true?</p> <p>13 A. True.</p> <p>14 Q. Okay.</p> <p>15 A. But I did look at that paper.</p> <p>16 MR. BALL: That's all the</p> <p>17 questions we have. Our time is up so.</p> <p>18 MR. MATTHEWS: We'll get a</p> <p>19 rough, and send me everything they</p> <p>20 get.</p> <p>21 (Deposition concluded at 2:28 p.m.)</p> <p>22 -----</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 297</p> <p>1 INSTRUCTIONS TO WITNESS</p> <p>2</p> <p>3 Please read your deposition over</p> <p>4 carefully and make any necessary corrections.</p> <p>5 You should state the reason in the</p> <p>6 appropriate space on the errata sheet for any</p> <p>7 corrections that are made.</p> <p>8 After doing so, please sign the</p> <p>9 errata sheet and date it. You are signing</p> <p>10 same subject to the changes you have noted on</p> <p>11 the errata sheet, which will be attached to</p> <p>12 your deposition.</p> <p>13 It is imperative that you return</p> <p>14 the original errata sheet to the deposing</p> <p>15 attorney within thirty (30) days of receipt</p> <p>16 of the deposition transcript by you. If you</p> <p>17 fail to do so, the deposition transcript may</p> <p>18 be deemed to be accurate and may be used in</p> <p>19 court.</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>

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